UNION EUROPEENNE

Bruxelles, le 14 MAI 2007
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Subject: **General session of the OIE May 2007**

Dear Director General,

Please find attached, for your informal information, an annex indicating the intended position of the Community including written comments on the report of the Aquatic Animal Health Standards Commission to be raised at the General Session in May 2007 in Paris.

Concerning the report of the Biological Standards Commission I would like to advise you that the Community agrees with the listing and updates for the new applications for OIE Reference Laboratories and Collaborating Centres etc and also with the proposed amended chapters for the diagnostic manual for a vote during the General Session.

I trust you will find this useful.

Thank you for your continued cooperation

Kind regards,

Pr Dr Werner ZWINGMAN	Mrs Paola TESTORI-COGGI
CVO of Germany	*Acting Deputy Director General*

Annex: 1

Copy: All Directors/Chief Veterinary Officers of the Community, Croatia, Iceland, Norway, Switzerland and Turkey.

Dr. B. Vallat
Directeur général OIE
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ANNEX

75th General Session International Committee
World organisation for animal health Paris, 20-25 May 2007

75 SG/12/CS4 B

Original: English
March 2007

REPORT OF THE MEETING OF THE OIE AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 5-9 March 2007

The OIE Aquatic Animal Health Standards Commission (hereafter referred to as the Aquatic Animals Commission) met at the OIE Headquarters from 5 to 9 March 2007. The meeting was chaired by Dr Eva-Maria Bernoth, President of the Commission, and Dr Ricardo Enriquez, Secretary General, acted as Rapporteur. Participants are listed at Appendix I. The adopted Agenda is given at Appendix II.

Dr Bernard Vallat, Director General of the OIE, welcomed the participants of the meeting and thanked them for their dedicated and continuing good work. He informed the Aquatic Animals Commission on the ongoing discussions in regard to closer collaboration between the OIE and the Food and Agriculture Organization of the United Nations (FAO). A chart describing the respective roles and competencies has been prepared by the OIE and endorsed by the FAO Director General after discussion with FAO staff.and the OIE Administrative Commission.

Dr Vallat illustrated the progress the OIE is making in assisting Member Countries in capacity building activities through the use of the Performance, Vision and Strategy (PVS) tool. More than 70 certified experts have been trained by the OIE to conduct PVS evaluations in Member Countries. He explained that the OIE could perform an evaluation in a Country only after receiving an invitation from its OIE Delegate; 40 Member Countries have already requested an evaluation by the OIE. Dr Vallat explained that the OIE proposed to extend the application of the PVS to aquatic animal health services and invited the Aquatic Animals Commission to involve itself in this work.

Dr Vallat explained that the OIE intends to submit to the next International Committee a list of antimicrobials of veterinary importance. This list includes antimicrobials used in aquaculture. Dr Vallat thanked the Aquatic Animals Commission for its contribution and stated that the OIE will recommend prudent use of these antimicrobials in order to minimise the risk of development of antimicrobial resistance while safeguarding access to products needed for animal health.

Dr Vallat noted the significant number of responses from Member Countries on the questionnaire on amphibian trade and diseases and the generally positive support for including amphibians in the remit of the OIE. Dr Vallat recommended the Aquatic Animals Commission bring recommendations on this issue to the May 2007 OIE General Session.

Finally Dr Vallat thanked the Aquatic Animals Commission's members for their contribution to the OIE Regional Conferences and underlined the importance of continuously updating the presentations so to convey relevant political messages. He encouraged the continuation of this practice to inform OIE Delegates about OIE activities in the field of aquatic animal health and trade.

The Aquatic Animals Commission recognised the contribution of the following Member Countries in providing comments: Argentina, Australia, Canada, Colombia, the European Community (EC), Japan, Madagascar, Nicaragua, Norway, Switzerland, Taipei China, Thailand and the United States of America (USA).

The Aquatic Animals Commission examined various *Aquatic Animal Health Code* (hereafter referred to as the *Aquatic Code*) draft texts from its October 2006 report in the light of Member Countries' comments. The outcome of the Aquatic Animals Commission's work is presented as Appendices III to XXX to this report. Additions made during the October 2006 meeting are shown as double underlined text, with deleted text in strikeout, and those made at this meeting (March 2007) in a similar fashion but with a coloured background to distinguish the two groups of proposals.

Member Countries are invited to submit their comments to the OIE on Appendices XXIII to XXX of this report prior to 6 August 2007. The comments should be sent preferably by electronic mail to the following address: trade.dept@oie.int. The Aquatic Animals Commission will address the comments received at its next meeting.

The table below summarises the texts that will be proposed – as presented in the appendices – to the OIE International Committee for adoption at the 75th General Session (first part), the texts that are presented for Member Countries' comment (second part), and texts for Member Countries' information (third part). A blank appendix was inserted to keep the numbering of appendices consistent with that of the October 2006 report.

Appendices proposed for adoption at the 75th General Session	**Appendix number**
Definitions (Ch. 1.1.1.)	Appendix III
Diseases listed by the OIE (Ch. 1.2.3.)	Appendix IV
Zoning and compartmentalisation (Ch. 1.4.4.)	Appendix V
Infection with *Bonamia ostreae* (Ch. 2.2.1.)	Appendix VI
Infection with *Bonamia exitiosa* (Ch. 2.2.2.)	Appendix VII
Infection with *Haplosporidium nelsoni* (Ch. 2.2.3.)	Appendix VIII
Infection with *Marteilia refringens* (Ch. 2.2.4.)	Appendix IX
Infection with *Mikrocytos mackini* (Ch. 2.2.5.)	Appendix X
Infection with *Xenohaliotis californiensis* (Ch. 2.2.8.)	Appendix XI
Recommendations for transport (Ch. 1.5.1.)	Appendix XII
Blank Appendix	Appendix XIII
Koi herpesvirus disease (Ch. 2.1.17.)	Appendix XIV
Taura syndrome (Ch. 4.1.1.)	Appendix XV
White spot disease (Ch. 4.1.2.)	Appendix XVI
Yellowhead disease (Ch. 4.1.3.)	Appendix XVII
Tetrahedral baculovirosis (Ch. 4.1.4.)	Appendix XVIII
Spherical baculovirosis (Ch. 4.1.5.)	Appendix XIX
Infectious hypodermal and haematopoietic necrosis (Ch. 4.1.6.)	Appendix XX
Crayfish plague (Ch. 4.1.7.)	Appendix XXI
Koi herpesvirus disease (*Aquatic Manual* Chapter)	Appendix XXII
Appendices for Member Countries' comments (deadline 6 August 2007)	**Appendix number**
Infectious myonecrosis (Ch. 4.1.9.)	Appendix XXIII
Necrotising hepatopancreatitis (Ch. 4.1.10.)	Appendix XXIV
White tail disease (Ch. 4.1.11.)	Appendix XXV
Hepatopancreatic parvovirus disease (Ch. 4.1.12.)	Appendix XXVI
Mourilyan virus disease (Ch. 4.1.13.)	Appendix XXVII
Guidelines for the control of aquatic animal health hazards in aquatic animal feeds	Appendix XXVIII
General guidelines for aquatic animal health surveillance (*Aquatic Code* Appendix)	Appendix XXIX
Guidelines for aquatic animal health surveillance (*Aquatic Manual* Chapter)	Appendix XXX

Appendices for Member Countries' information	Appendix number
Report of the *ad hoc* Group on Aquatic Animal Feeds	Appendix XXXI
Report of the *ad hoc* Group on Aquatic Animal Health Surveillance	Appendix XXXII
Conclusions and abstracts from workshop in Florianopolis	Appendix XXXIII
Work plan	Appendix XXXIV

1. **Activities and progress of *ad hoc* Groups**

The Aquatic Animals Commission reviewed the progress made by those *ad hoc* Groups that have met since the previous meeting of the Commission:

I. OIE *ad hoc* Group on Aquatic Animal Health Surveillance, 24-26 July 2006 and 29-31 January 2007.

II. OIE *ad hoc* Group on Aquatic Animal Feeds, 12-14 December 2006.

The Commission noted the overall progress made by the *ad hoc* Groups against their terms of reference and expressed its appreciation for the excellent work of the experts involved. The Commission recognised the efficiency of face-to-face meetings and agreed that this way of working should be continued.

Specific items related to the above *ad hoc* Groups will be dealt with in specific agenda items below.

2. ***Aquatic Animal Health Code***

Community Position

The European Community appreciates the efforts done by the OIE AAC with respect to amendments of the Code. The Community also welcomes the explanation by the OIE AAC on their assessment of the comments received in points 2.1 –2.7 and 7.1. This ensures greater transparency.

The Community maintains its concern about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in this case the ICES guidelines) because of the lack of clarity of the validity of such external documents and any changes made to. However, the Community welcomes the OIE initiative to establish more formal arrangements between ICES and the OIE.

In addition, the Community would ask the OIE AAC to re-consider its position to request freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products (crustacean products, non-viable molluscs or mollusc products, as well as eviscerated fish products). Taking into account their intended use and the nature of the commodities (which by nature cannot be for further farming), seems unjustified.

Finally, concerning the trade of disinfected fish eggs, the Community would encourage the OIE to draft a specific chapter in the OIE Code addressing the certification requirements and conditions to be met to facilitate the safe trade as regards certain diseases. To address the same objective the Community fully support the OIE initiative to update the egg disinfection procedures in the Manual. The Community submitted the bibliographical review "Fish egg trade" (EU funded project) to support the ongoing work in this field.

2.1. General comments on the October 2006 report

Nicaragua had suggested using the name *Litopenaeus vannamei* instead of *Penaeus vannamei* in Article 2 of the crustacean disease chapters. The Aquatic Animals Commission discussed this request but decided to maintain the previous nomenclature as recommended by leading experts. See following references:

ALDERMAN D.J., COSTA-PIERCE B.A., DONALDSON E.M., HULATA G. & WILSON R.P. (2007). - Editorial: Use of the generic name Penaeus. *Aquaculture, in press*.

FLEGEL T.W. (2007). - The right to refuse revision in the genus Penaeus. *Aquaculture*, 264: 2-8.

Colombia drew the Commission's attention to the rapid expansion of aquaculture of warm water fish species (e.g. tilapia) and suggested that the *Aquatic Code* refer to diseases of those species and also that health conditions be revised. The Commission pointed out that the *Aquatic Code* chapters on individual diseases apply to all species listed as susceptible in the scope of those chapters, including warm water or ornamental varieties as applicable.

The Commission welcomed the suggestion made by the EC on the pathways for infected compartments to again be declared free from the disease in question. Considering the ongoing discussions related to the Chapter on zoning and compartmentalisation (see point 2.5 below), the Commission decided to await the adoption of the draft chapter prior to formulating any specific recommendations on this topic.

The EC queried the need for animal health certificates for dead molluscs, fish and crustacean products. The Commission points out that for those commodities that are considered safe, and therefore listed in Article 3, point 1) of each disease chapter, there is no need to provide an animal health certificate. Furthermore a health certificate is currently recommended only for those products originating from a country, zone or compartment declared free from the diseases under consideration, to provide confirmation of the claim of free status to the importing country.

The EC also suggested combining the articles "Importation of aquatic animal products from an area not declared free" and "Importation of aquatic animal products from an area declared free" into one single article. In line with the above, the Commission points out that maintaining two separate articles makes the different requirements of each easier to understand.

In support of their previous request to consider disinfected fish eggs as safe commodities for some diseases, the EC has provided the report of the EU funded study "Fish Egg Trade". The Commission agreed with the EC comment that it would be useful to have in the OIE *Manual of Diagnostic Tests for Aquatic Animals* (hereafter referred to as the *Aquatic Manual*) full details of step by step procedures for the disinfection of eggs. The Commission will ask the consultant editor for the *Aquatic Manual* to redraft the egg disinfection section on Chapter 1.1.5. Once this task is completed, the Commission will forward the consultant editor's revision as well as the report of the EU funded study "Fish Egg Trade" to the OIE *ad hoc* Group on Chapters for Fish Diseases for the OIE *Aquatic Animal Health Code* for consideration and formulation of a recommendation on whether disinfected fish eggs could be listed under Article 3 of the specific disease chapter.

The EC raised concerns about the suggested references in the *Aquatic Code* to the ICES Code of Practice on the Introductions and Transfers of Marine Organisms. The Commission stressed that the ICES Code is an internationally recognised document which has been in existence for many years and has been successfully applied globally. The Commission noted that the practice of cross referencing to non OIE international standards is used in other OIE texts. The Commission noted that methods for disease prevention and control are within the mandate of the OIE; it also noted that the scope of the ICES Code goes beyond development of specific pathogen free populations and includes procedures for introducing new species while mitigating the risk of introduction of disease. Hence the Commission considers it appropriate to refer to the ICES Code. Furthermore, given the relevance of the ICES Code to the OIE mandate, the OIE Central Bureau may wish to look at the possibility of establishing more formal arrangements between ICES and the OIE.

The EC and Canada commented on the explanatory note for disease chapters on diseases that have been removed from the OIE list. To better identify these diseases for which specific disease chapters are nevertheless retained in the *Aquatic Code*, despite their removal from the list of diseases in Chapter 1.2.3., the Aquatic Animals Commission proposes to amend the explanatory note as follows: "NB: This disease does not meet the listing criteria in Chapter 1.2.2. Nevertheless, reporting requirements for non listed diseases apply in regard to significant epidemiological events (Article 1.2.1.3, point 1e)".

2.2. Definitions (Chapter 1.1.1.)

Community position

The Community supports the proposal for this Chapter in Appendix III but would like the written comments which have been highlighted in the Appendix taken into account at the next meeting of the Code Commission to improve the text.

Several Member Countries expressed concern with the proposed definition of "veterinary paraprofessionals". The Aquatic Animals Commission noted that the proposed definition is based on the current definition in the OIE *Terrestrial Animal Health Code* (hereafter referred to as the *Terrestrial Code*) and will liaise with the Terrestrial Code Commission prior to any modifications to the proposed definition. The draft definition will therefore not be submitted for adoption at the 75th General Session in May 2007.

In response to a suggestion from Australia, the Commission modified several other definitions that cross reference to the term "infection" to accommodate the newly proposed term "infestation".

Some comments were received on the French and Spanish translations of certain proposed definitions. The Commission referred these comments to the OIE Central Bureau.

Several other comments received were addressed by the Commission in their review of the proposed definitions.

The definitions that will be proposed to the OIE International Committee for adoption at the 75th General Session in May 2007 are attached at Appendix III.

2.3. Criteria for listing aquatic animal diseases (Chapter 1.2.2.)

The Aquatic Animals Commission addressed a comment from Chile proposing an amendment to criterion 7 (geographic distribution) of the disease listing criteria so that it specifies the number of countries that must be free of the disease for this criterion to apply. The Commission discussed this issue but is of the opinion that the application of that criterion needs to take into account the different variables of specific situations (distribution of the susceptible species, climate) on a case by case approach. Therefore, the Commission does not propose any changes to this Chapter.

2.4. Revision of the list of diseases (Chapter 1.2.3.)

Community Position

The Community supports the proposal for this Chapter in Appendix IV.

Argentina expressed concerns about the removal of infectious pancreatic necrosis (IPN) from the OIE list of diseases arguing that IPN is one of the diseases with the highest impact on aquatic animal trade, both in terms of economics and production. The Aquatic Animals Commission reminds Argentina that the OIE International Committee adopted the removal of IPN from the list of diseases in May 2006; however, an *Aquatic Code* chapter on IPN has been retained to provide guidance for trade.

Japan recommended the delisting of abalone viral mortality because of the absence of a specific diagnostic test and consequent difficulties with reporting. The Commission pointed out that the OIE International Committee adopted the listing of abalone viral mortality in May 2006. The Commission acknowledges that the diagnosis of diseases in this syndrome is problematic, but the only way to gather additional information is by making the disease notifiable. As previously stated, all diseases listed as emerging diseases will be reviewed within three years of their listing to decide whether they now meet the full listing criteria or whether they should be recommended for deletion.

The Commission agreed that further scientific information has become available since the last meeting of the OIE *ad hoc* Group on the OIE List of Aquatic Animal Diseases and that a revision of the disease card on this disease may be necessary (see point 9.1 below). The Commission pointed out that, at this stage, the *Aquatic Code* does not contain any recommendations related to trade and abalone viral mortality.

Nicaragua commented against the proposed listing of necrotising hepatopancreatitis (NHP) since therapeutic methods are readily available. The Commission pointed out that the availability of therapeutic treatment is not part of the listing criteria. On the other hand managerial procedures can mitigate the losses due to the pathogen; therefore the disease will need to be reassessed against Criterion 1 by the OIE *ad hoc* Group on the OIE List of Aquatic Animal Diseases. The Commission therefore proposes to maintain NHP as under study pending the recommendations of the *ad hoc* Group.

Madagascar commented that hepatopancreatic parvovirus (HPV) disease should not be listed because it causes neither massive mortality nor significant production losses in well managed systems. Because multiple strains of HPV exist that are not detectable by the available diagnostic methods, a robust diagnostic test still needs to be developed. The Commission decided that the disease will need to be reassessed against the listing criteria by the OIE *ad hoc* Group on the OIE List of Aquatic Animal Diseases. The Commission therefore proposes to list HPV disease as under study pending the recommendations of the *ad hoc* Group.

The USA considers the listing of Mourilyan virus disease premature due to the paucity of scientific literature linking the virus to a distinct disease (see Criterion 2 of Article 1.2.2.2.). The Commission decided that the disease will need to be reassessed against the listing criteria by the OIE *ad hoc* Group on the OIE List of Aquatic Animal Diseases. The Commission therefore proposes to list Mourilyan virus disease as under study pending the recommendations of the *ad hoc* Group.

The updated Chapter on the Diseases Listed by the OIE that will be proposed to the OIE International Committee for adoption at the 75th General Session in May 2007 is attached at Appendix IV.

2.5. Zoning and compartmentalisation (Chapter 1.4.4.)

Community Position

The Community supports the proposal for this Chapter in Appendix V.

The Aquatic Animals Commission revised the draft chapter taking into account Member Countries' comments.

The updated Chapter on Zoning and Compartmentalisation that will be proposed to the OIE International Committee for adoption at the 75th General Session in May 2007 is attached at Appendix V.

2.6. Recommendations for transport (Chapter 1.5.1.)

Community Position

The Community supports the proposal for this Chapter in Appendix XII but would like the written comments which have been highlighted in the Appendix taken into account at the next meeting of the Code Commission to improve the text.

The Aquatic Animals Commission revised the draft chapter taking into account Member Countries' comments.

Norway suggested animal welfare be taken into account in relation to transport of fish. The Commission noted the ongoing work on aquatic animal welfare during transport that is being addressed by the OIE Working Group on Animal Welfare (see point 2.9 below for more details).

Norway and the EC suggested further work be done on biosecurity risks associated with transport by sea. The Commission agreed with this suggestion, accepted Norway's offer to assist and invited Norway to submit a draft text for consideration by the Commission.

The updated Chapter on recommendations for transport that will be proposed to the OIE

International Committee for adoption at the 75th General Session in May 2007 is attached at Appendix XII.

2.7. Disease chapters (Part 2)

Community Position (pending approval by CVOS)

1) The Community supports the proposal for these Chapters in Appendixes VI-XI, XIV-XX but would like the written comments which have been highlighted in the Appendix taken into account at the next meeting of the Code Commission to improve the text.

2) Concerning Appendix XXI, on Crayfish plague the Community cannot support the proposal since a major unfounded amendment has been proposed. . The only way given to obtain the status of disease free country, zone or compartment is the absence of any susceptible species. This seems to be defeating the object of achieving free status.

3) With regard to the inclusion in the mollusc chapters of the larvae as a safe commodity we would argue that to our best knowledge, there is no scientific evidence that proves its safety.Therefore, we would propose the OIE the non-inclusion of the larvae as safe commodities until a sound scientific evidence has been found

Australia and the OIE Reference Laboratory for Infection with *Bonamia exitiosa*, Infection with *Bonamia ostreae*, Infection with *Mikrocytos roughleyi*, Infection with *Marteilia refringens* and Infection with *Marteilia sydneyi* commented on the basis for establishing timeframes recommended for basic biosecurity conditions in mollusc disease chapters. The Aquatic Animals Commission explained that the timeframes for these conditions were proposed on the basis of the biology and lifecycles of the agent and susceptible species, the requirement for and presence of intermediate hosts, and direct transmission and incubation periods. However, the Commission acknowledges that other factors could be considered and agreed to ask the OIE *ad hoc* Group on Aquatic Animal Health Surveillance to propose what criteria should be used for establishing timeframes for all disease chapters.

Several comments suggested that larvae should not be listed in Article 3 point 1a) of some mollusc disease chapters. The Commission noted that the argument put forward is more relevant to spat and juvenile stages than larvae. The Commission decided to maintain the current recommendation for the time being but, realising the complexity of this issue, agreed to forward these comments to the OIE *ad hoc* Group on Chapters for Mollusc Diseases for the OIE *Aquatic Animal Health Code* for disease-by-disease consideration.

Taipei China asked to specify the inactivation temperatures for “heat treated products” in Article 3 point 1a) of all mollusc disease chapters. The Commission pointed out that the comment referred to an already approved text in the *Aquatic Code* but proposed, based on expert opinion, to replace the reference to “heat treated” with “pasteurised”.

The Commission reviewed further Member Countries’ comments on the proposed disease chapters on mollusc diseases and amended the draft chapters where necessary.

The updated Chapters on mollusc diseases that will be proposed to the OIE International Committee for adoption at the 75th General Session in May 2007 are attached at Appendices VI to XI.

The Commission reviewed Member Countries’ comments on the draft disease chapter on gyrodactylosis and agreed that there was merit with many of the points raised, but due to the highly technical, scientific nature of these comments, decided to refer them to the OIE *ad hoc* Group on Chapters for Fish Diseases for the OIE *Aquatic Animal Health Code*. This draft chapter will not be proposed therefore for adoption at the May 2007 General Session.

The Commission reviewed Member Countries’ comments on the draft disease chapter on koi herpesvirus (KHV) disease, agreed with many of the points raised and made some changes to several articles accordingly. For example, Article 2.1.17.3. was changed to clarify the nature of some commodities, e.g. fish meal intended for use in animal feeds. The updated Chapter on KHV disease that will be proposed to the OIE International Committee for adoption at the 75th General Session in May 2007 is attached at Appendix XIV.

Taipei China pointed out a discrepancy regarding the causative agent for white tail disease between the *Aquatic Code* and the disease card. The Commission clarified that the text in the *Aquatic Code* is the correct one and asked the OIE Central Bureau to amend the disease card.

Taipei China asked for more detail on the inactivation parameters for dry feeds mentioned in Articles 3 of the crustacean disease chapters. The Commission indicated that more details are provided in the report of the *ad hoc* Group on Aquatic Animal Feeds (see point 2.11 below).

Dr David Alderman, designated OIE expert for the OIE Reference Laboratory on Crayfish plague, joined the meeting for this item. The Commission reviewed in detail the draft chapter on crayfish plague and agreed on several changes due to the different nature of this disease in comparison to the other crustacean diseases.

The updated Chapters on crustacean diseases that will be proposed to the OIE International Committee for adoption at the 75th General Session in May 2007 are attached at Appendices XV to XXII.

The draft Chapters on Infectious myonecrosis, white tail disease, NHP, HPV and mourilyan virus disease are presented at Appendices XXIII to XXVII for Member Countries' comment.

2.8. New appendix on general guidelines for aquatic animal health surveillance the

See point 7.3 below.

2.9. Aquatic animal welfare

The Aquatic Animals Commission awaits feedback from the OIE Animal Welfare Working Group on issues previously raised by Member Countries.

2.10. Antimicrobial resistance in the field of aquatic animals

The Aquatic Animals Commission reviewed the list of antimicrobials of veterinary importance that had been compiled by the OIE *ad hoc* Group on Antimicrobial Resistance (which reports to the Biological Standards Commission) and the comments on it that had been sought from aquatic experts. The Commission made some minor changes to better reflect the relative importance of some groups on antimicrobials for aquatic animals. The amended document will be referred back to the Biological Standards Commission for consideration prior to presentation at the 75th General Session.

2.11. Aquatic animal feeds

Prof. Eli Katunguka-Rwakishaya, Member of the Aquatic Animals Commission, reported on the progress made by the OIE *ad hoc* Group on Aquatic Animal Feeds (the report is appended at Appendix XXXI for Member Countries' information). The Aquatic Animals Commission was impressed by the useful work of the *ad hoc* Group on these complex issues.

The Commission discussed the Draft Guidelines for the Control of Aquatic Animal Health Hazards in Aquatic Animal Feeds and made some minor modifications to the text which is appended at Appendix XXVIII for Member Countries' comments.

The Commission noted the *ad hoc* Group's query about the proposed scope of the draft Guidelines. The Commission agreed that the *ad hoc* Group should – as a priority –complete its work on aquatic animal pathogens through a further meeting. The timing of this meeting should be organised to allow for the *ad hoc* Group to consider Member Countries' comments received after the May 2007 General Session. Additional work could take place on hazards of public health significance, but the Commission recommended that this be done under the auspices of the OIE Animal Production Food Safety Working Group.

2.12. Diseases of amphibians

Community Position

The Community supports the inclusion of the amphibian diseases under the scope of the Aquatic Code.

The Aquatic Animals Commission reviewed the outcomes of the questionnaire on amphibian diseases and was pleased with the replies received. The Commission noted that of the 65 countries that had replied, 46 supported the inclusion of amphibian diseases in the remit of the OIE. In view of this supportive majority, the Commission proposes to ask the OIE International Committee at the 75th General Session in May 2007 for in-principle agreement to this expansion of the OIE's remit. If agreement is reached, the Commission proposes to reconvene the OIE *ad hoc* Group on Amphibian Diseases, with revised terms of reference that include the development of a list of diseases and draft chapters for the *Aquatic Code* and the *Aquatic Manual*.

3. Joint meeting with the President of the OIE Terrestrial Animal Health Standards Commission

Dr Alex Thiermann, President of the OIE Terrestrial Animal Health Standards Commission (hereafter referred to as the Terrestrial Code Commission), joined the meeting for this agenda item.

3.1. Model certificates

Dr Thiermann reported on the progress made by the OIE *ad hoc* Group on the Revision of the Model Certificates. The revised models will be discussed at the next meeting of the Terrestrial Code Commission, with the view of circulating them for Member Countries' comments.

The Aquatic Animals Commission reviewed the revised model certificates and expressed support for the approach taken. The Commission will follow developments (including the feedback from Member Countries) of these models with a view to revising the aquatic model certificates along similar lines.

3.2. Handling and disposal of carcasses and wastes of aquatic animals

Prof. Katunguka-Rwakishaya presented to the Aquatic Animals Commission a new draft Appendix for the *Aquatic Code* on General Guidelines for Disposal of Dead Aquatic Animals and Wastes of Aquatic Animals. This draft takes into account the current Appendix 3.6.6. in the *Terrestrial Code*. Issues relating to welfare will be handled in due course based on the recommendations of the Animal Welfare Working Group. The Commission thanked Prof. Katunguka-Rwakishaya for his work and provided some comments. Prof. Katunguka-Rwakishaya will provide a revised draft for consideration for the next meeting of the Commission, with a view to then circulating it for Member Countries' comments.

3.3. Future evolution of both Codes

Dr Thiermann explained that due to the size of the printed edition of the *Terrestrial Code*, OIE plans to publish the next edition as two volumes. This separation requires a structural reorganisation of the chapters rather than just splitting the book in two. Representative examples will be presented to the next General Session for demonstration.

While future editions of the horizontal chapters of both the *Aquatic* and *Terrestrial Codes* could be merged into one volume, the Aquatic Animals Commission is firmly of the view that harmonising the content of both Codes is a higher priority than merging into one single volume; first there are concepts that are sufficiently different in application (e.g. zones) to make merging of horizontal chapters unnecessarily complicated and difficult to apply. Furthermore, the benefit to the different groups of end users (i.e. aquatic or terrestrial) of such merging is not apparent. Where appropriate, the contents of the horizontal chapters of both Codes will be identical.

3.4. Performance, Vision and Strategy tool

The Aquatic Animals Commission was updated on the OIE activities related to the PVS and

received a copy of the PVS tool and manual. The Aquatic Animals Commission acknowledged the intent of the OIE to extend the application of the PVS to aquatic animal health services and a proposal to offer training to potential assessors of aquatic animal health services. The Commission noted the training could take place later this year.

The PVS tool is designed to assist Veterinary Services to establish their current level of performance, to identify gaps and weaknesses regarding their ability to comply with OIE international standards, to form a shared vision with stakeholders (including the private sector) and to establish priorities and carry out strategic initiatives.

The Aquatic Animals Commission welcomed the principles expressed in the PVS and its future extension to aquatic animal health but recommended that due consideration be given to adapting the tool to make it broadly applicable to aquatic animal health (e.g. the central role of the veterinarians, the issue of accreditation of laboratories and experts, application of zones and compartments, traceability of animals, food safety, certification).

The Commission suggested that in adapting the tool, the provisions of the *Aquatic Code* (e.g. Evaluation of the Competent Authorities) need to be used as a legal basis for the aquatic PVS.

The OIE *ad hoc* Group on the Evaluation of Veterinary Services will meet in July 2007 and will continue the work on the development of the PVS. The Aquatic Animals Commission will suggest to the OIE Central Bureau to send a representative to this meeting and recommended that the OIE convene a specific *ad hoc* Group to develop the aquatic PVS. The Aquatic Animals Commission will also provide a list of potential candidates acquainted with aquatic animal health services as potential trainees as PVS evaluators.

4. **Feedback from the Commission on the OIE World Animal Health Information Database (WAHID)**

Dr Karim Ben Jebara, Head of the OIE Information Department, joined the meeting for this agenda item.

The Aquatic Animals Commission provided feedback on its experience on using the various features of WAHID for information on the occurrence of aquatic diseases in Member Countries. The Commission was impressed by the appearance and the ease of use of the new system.

Dr Ben Jebara demonstrated several features of WAHID and explained that further refinement is taking place in response to feedback from users. For example the Information Department is working on the possibility for displaying information on aquatic diseases separately from that on terrestrial diseases in addition to the current combined manner.

The Commission noted that although links to disease cards are provided for some of the terrestrial animal diseases, no such links are yet provided for the aquatic animal diseases. The Commission requested that links be provided and Dr Ben Jebara agreed that this would be done as soon as practicable.

5. **OIE *Scientific and Technical Review*: Issue on aquatic animal health**

Dr Paul-Pierre Pastoret, Head of the OIE Publications Department, joined the meeting for this agenda item.

He reported good progress on the preparation of the OIE *Scientific and Technical Review*: Changing trends in managing aquatic animal disease emergencies, which is due to be published in April 2008.

6. **The role and activities of the OIE in the field of aquatic animal health**

6.1. International meetings

6.1.1. Regional Commissions Conferences

The Conference of the OIE Regional Commission for Africa took place in Eritrea, Asmara from 26 February to 1 March 2007. Prof. Katunguka-Rwakishaya represented the Aquatic Animals Commission and presented a paper “Update on the activities of the Aquatic Animal

Health Standards Commission''. The paper emphasized the following areas:

- Importance of aquaculture as the fastest growing animal food producing industry
- The need to control and prevent spread of listed diseases (*Aquatic Code* and *Aquatic Manual*)
- The need for veterinary authorities of Member Countries to take a keener interest in aquatic animal diseases
- Better cooperation between veterinary and fisheries authorities in the control and reporting of aquatic diseases.

The paper was well received and discussed broadly. Dr Barry O'Neil, President of the OIE International Committee, Dr Robert Thwala, President of the OIE Regional Commission for Africa, and Dr Dewan Sibartie, Head of the OIE Regional Activities Department, called upon Delegates to seriously consider the issues raised in the presentation.

The 18th Conference of the OIE Regional Commission for the Amercias took place in Brazil, Florianopolis from 28 November – 2 December 2006. Dr Enriquez presented an update of the activities of the OIE related to the Aquatic Animals.

Dr Enriquez underlined the importance of receiving comments from Member Countries on the proposals of the Commission especially those regarding the amendments to be made in the *Aquatic Code* and the *Aquatic Manual*. He pointed out that a national focal point for aquatic animal diseases was imperative to improve such exchange of information.

At the end of his presentation, Dr Enriquez stated that the communication with the Animal Health Information Department on the OIE World Animal Health Information System has been particularly fruitful.

The Commission committed to provide input at the upcoming Conferences of the OIE Regional Commission for the Middle-East (October 2007) and the OIE Regional Commission for Asia, the Far East and Oceania (November 2007).

6.1.2. Fifth Annual General Meeting of NACA's Asia Regional Advisory Group on Aquatic Animal Health, 22-24 November 2006, Bangkok, Thailand

Dr Bernoth attended this three-day meeting which addressed global and regional aquatic animal health issues. She presented a report on the outcomes of the OIE General Session in May 2006 and new initiatives underway in aquatic animal health. Topics covered at the meeting included an update on emerging crustacean, fish and mollusc diseases in the region and regional and international cooperation in Asian aquatic animal health management. The NACA/OIE quarterly aquatic animal disease reporting system was reviewed.

The full report of the meeting has been sent to National Coordinators and OIE Aquatic Focal Points and OIE Delegates in the 21 participating countries in the Asia Pacific. The meeting acknowledged the collaboration with the OIE Central Bureau and with the OIE Regional Official as well as the Commission, who all have contributed to significantly strengthening aquatic animal disease control and management in the Asian region.

6.1.3. First International Conference of OIE Reference Laboratories and Collaborating Centres, 3-5 December 2006, Florianopolis, Brazil

Dr Gideon Brückner, Head of the OIE Scientific and Technical Department, joined the meeting for this and the following agenda item.

The Conference had been a success; over 300 participants from 35 countries had attended.

Dr Brückner presented the recommendations, which would be published in the Conference proceedings.

The new OIE laboratory twinning concept had been launched at the Conference and was well received. However, participants stressed that for the twinning to be successful, funding would need to be found for both the twinned laboratory and to cover the additional costs for OIE Reference Laboratories. The Commission welcomed the laboratory twinning initiative and encouraged Member Countries to consider their twinning opportunities. Dr Brückner informed the Commission that the Delegates would shortly be sent documentation outlining procedures for applications to the OIE. The Commission recommended that the OIE Reference Laboratories and Collaborating Centres also be sent this information.

6.1.4. OIE Global Conference on Aquatic Animal Health, 9-12 October 2006, Bergen, Norway

The OIE, in collaboration with the Norwegian Government, organised the first Global Conference on Aquatic Animal Health dedicated to reinforcing the commitment of OIE Member Countries to their rights and obligations regarding disease notification and implementation of OIE standards.

The Commission endorsed the draft recommendations to Member Countries and to the OIE on aquatic animal health issues, which had been formulated at the Conference. These recommendations will be included in the proceedings and will be reported to the OIE International Committee at the 75th General Session in May 2007.

6.2. Cooperation with FAO

The Aquatic Animals Commission noted the exchange of correspondence between the OIE and the FAO on the topic of aquatic animal health. The Commission will continue to work with the OIE Central Bureau to support further strengthening of the collaboration between the OIE and the FAO.

7. ***Manual of Diagnostic Tests for Aquatic Animals***

7.1. Koi herpesvirus disease

Community Position

The Community supports the proposal for this Chapter in Appendix XXII but would like the written comments which have been highlighted in the Appendix taken into account at the next meeting of the Code Commission to improve the text.

Comments had been received on the draft chapter on KHV disease that had been appended to the last meeting's report. The Aquatic Animals Commission was grateful for the constructive and helpful comments which were referred to the author who made a number of amendments to the chapter. This amended version will be proposed for adoption at the General Session in May and, if adopted, will be added to the web version of the *Aquatic Manual*.

The new Chapter on KHV disease that will be proposed to the OIE International Committee for adoption at the 75th General Session in May 2007 is attached at Appendix XXII.

7.2. Update from the Consultant Editor

Dr David Alderman, the newly appointed Consultant Editor for the *Aquatic Manual*, joined the meeting for this agenda item.

One of the Terms of Reference for the Consultant Editor is to revise the design of the disease chapter template. Dr Alderman agreed to reformat the template in time for the next meeting of the Commission in the second half of 2007, taking into account the updated template prepared by the OIE *ad hoc* Group on Aquatic Animal Health Surveillance (see point 2.8 above). Once the Commission approves the new template, it would be sent to the authors with the request to use it to update their chapters. The next edition of the *Aquatic Manual* is scheduled to be published in 2009.

It is planned to include in this edition updates of all the chapters, including those that were not updated in the 2006 edition.

7.3. Report of the meetings of the OIE *ad hoc* Group on Aquatic Animal Health Surveillance

The Aquatic Animals Commission noted the report of the *ad hoc* Group (which is appended at Appendix XXXII for Member Countries' information). The Commission was very impressed with the amount of progress made by the Group at its two meetings and the quality of the output.

Appendices VI and VII of the report of the *ad hoc* Group represent work in progress; the Commission will submit its comments to the *ad hoc* Group with the view to preparing texts for Member Country comment at the next meeting of the Commission.

Member Country comments are sought on Appendices XXIX and XXX.

7.4. Review of Chapter 1.1.5. on disinfection of aquaculture establishments

The current *Aquatic Manual* chapter on disinfection of aquaculture establishments is divided into three sections: one each for fish, mollusc and crustacean farms. This means that there is some repetition as the principles and some procedures are common to all three groups. Dr Alderman agreed to rearrange the chapter such that it begins with the general principles and procedures followed by specific procedures for fish, molluscs and crustaceans, e.g. fish eggs, crustacean broodstock, etc. The revised chapter will be reviewed by the Aquatic Animals Commission at its next meeting.

8. OIE Reference Laboratories

8.1. Review of list of Reference Laboratories

The Commission recommends acceptance of the following new applications for OIE Reference Laboratory status:

OIE Reference Laboratory for Koi herpesvirus disease

Fisheries Research Agency, Research Promotion & Development Department, Yokohama 220-6115, JAPAN Tel.: (+81-45) 227.2677; Fax: (+81-45) 227.2703; sanogen@fra.affrc.go.jp Designated Reference Expert: Dr Motohiko Sano.

OIE Reference Laboratory for Koi herpesvirus disease

Centre for Environment, Fisheries and Aquaculture Science (CEFAS), the Nothe, Weymouth, Dorset DT4 8UB, UNITED KINGDOM Tel.: (+44-1305) 206.639; Fax: (+44-1305) 206.601; keith.way@cefas.co.uk Designated Reference Expert: Dr Keith Way.

The OIE has been notified of the following changes of experts at OIE Reference Laboratories. The Commission recommends their acceptance:

Spring viraemia of carp

Dr Peter Dixon to replace Prof. Barry Hill at CEFAS, Weymouth, United Kingdom.

Crayfish plague (*Aphanomyces astaci*)

Dr Birgit Oidtmann to replace Dr David Alderman at CEFAS, Weymouth, United Kingdom.

The Commission acknowledged a request from the Delegate of the United Kingdom that the OIE Reference Laboratory for infectious pancreatic necrosis, at CEFAS, Weymouth be removed from the list.

The Commission was disappointed that it had not received any applications for OIE Reference Laboratory status for abalone viral mortality and once again encourages applications to be submitted through the OIE Delegate.

If the OIE International Committee adopts the listing of the crustacean diseases infectious myonecrosis and white tail disease in May 2007, OIE Delegates will be encouraged to submit applications for Reference Laboratories for these two diseases.

8.2. Concept paper on pathogen strain differentiation

Comments had been received from the USA on the concept paper (that was appended to the October 2006 report) strongly supporting this initiative and proposing guidelines to be included in the *Aquatic Manual*. The EC had also welcomed the concept paper and encourages OIE to pursue this issue.

The paper was presented at a special workshop held in conjunction with the First International Conference of OIE Reference Laboratories and Collaborating Centres (see point 6.1.3 above). The workshop reached the conclusion, endorsed in the recommendations of the conference, that this issue should be discussed in a wider forum at the next conference of OIE Reference Laboratories and Collaborating Centres and that the implications of differentiating between genotypes for OIE notification and reporting criteria should be considered by the Aquatic Animals Commission. The conclusions and abstracts from this workshop can be found at Appendix XXXIII for information of Member Countries.

8.3. Review of annual reports of activities (2006)

Reports had been received from all 28 Reference Laboratories and from the Collaborating Centre. The Aquatic Animals Commission was very impressed with the quality of the work carried out by the laboratories and appreciates the contributions they make towards achieving the objectives of the OIE.

9. **Any other business**

9.1. Disease cards

All the disease cards are available on the Aquatic Animals Commission web page under 'Disease Information'. Whilst discussing the format of the diseases cards, the Aquatic Animals Commission questioned the usefulness of disease cards for diseases for which an *Aquatic Manual* chapter already exists in print and on the web. The Commission is leaning towards having disease cards only for emerging and recently listed diseases for which there are not yet an *Aquatic Manual* chapter, and discontinuing cards for all other diseases. The Commission invites Member Country views on this proposition.

Australia queried the inclusion of abalone viral ganglioneuritis that occurred in Australia in the disease card on abalone viral mortality. The Commission acknowledged that since the update of that disease card, new research findings have become available on the Australian situation. The Commission invites Australia to submit such information to the Commission for consideration by the OIE *ad hoc* Group on the OIE List of Aquatic Animal Diseases, with the view to revise the disease card (in particular the case definition).

Comments had been received from Australia and the USA on the Mourilyan virus disease card. The USA queried the listing of this disease while Australia commented on the lack of specificity in the description of gross signs in the card. The Commission decided to propose the listing of Mourilyan disease as 'under study', but to keep the disease card until more information becomes available.

9.2. Work plan

The Aquatic Animals Commission reviewed its work plan for 2007–2008. The work plan is appended at Appendix XXXIV for Member Countries' information.

10. **Date of the next meeting**

The Aquatic Animals Commission proposed to meet on 1–5 October 2007.

.../Appendices

Appendix I

MEETING OF THE OIE

AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 5–9 March 2007

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Appendix II

MEETING OF THE OIE

AQUATIC ANIMAL HEALTH STANDARDS COMMISSION

Paris, 5-9 March 2007

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Adopted agenda

1. **Activities and progress of *ad hoc* Groups**
2. ***Aquatic Animal Health Code***
   - *2.1.* General comments on the October 2006 report
   - *2.2.* Definitions (Chapter 1.1.1.)
   - *2.3.* Criteria for listing aquatic animal diseases (Chapter 1.2.2.)
   - *2.4.* Revision of the list of diseases (Chapter 1.2.3.)
   - *2.5.* Zoning and compartmentalisation (Chapter 1.4.4.)
   - *2.6.* Recommendations for transport (Chapter 1.5.1.)
   - *2.7.* Disease chapters (Part 2)
   - *2.8.* New appendix on general guidelines for aquatic animal health surveillance
   - *2.9.* Aquatic animal welfare
   - *2.10.* Antimicrobial resistance in the field of aquatic animals
   - *2.11.* Aquatic animal feeds
   - *2.12.* Diseases of amphibians
3. **Joint meeting with the President of the Terrestrial Animal Health Standards Commission**
   - *3.1.* Model certificates
   - *3.2.* Handling and disposal of carcasses and wastes of aquatic animals
   - *3.3.* Future evolution of both Codes
   - *3.4.* Performance, Vision and Strategy tool
4. **Feedback from the Commission on the OIE World Animal Health Information Database (WAHID)**
5. **OIE *Scientific and Technical Review*: Issue on aquatic animal health**
6. **The role and activities of the OIE in the field of aquatic animal health**
   - *6.1.* International meetings
     - 6.1.1. Regional Commission Conferences
     - 6.1.2. Fifth Annual General Meeting of NACA's Asia Regional Advisory Group on Aquatic Animal Health, 22-24 November 2006, Bangkok, Thailand
     - 6.1.3. First International Conference of OIE Reference Laboratories and Collaborating Centres, 3-5 December 2006, Florianopolis, Brazil
     - 6.1.4. First OIE Global Conference on Aquatic Animal Health, 9-12 October 2006, Bergen, Norway
   - *6.2.* Cooperation with FAO

7. ***Manual of Diagnostic Tests for Aquatic Animals***
   - *7.1.* Koi herpesvirus disease
   - *7.2.* Update from the Consultant Editor
   - *7.3.* Report of the meetings of the OIE *ad hoc* Group on Aquatic Animal Health Surveillance
   - *7.4.* Review of Chapter 1.1.5 on disinfection of aquaculture establishments
8. **OIE Reference Laboratories**
   - *8.1.* Review of list of Reference Laboratories
   - *8.2.* Concept paper on pathogen strain differentiation
   - *8.3.* Review of annual reports of activities (2006)
9. **Any other business**
   - *9.1.* Disease cards
   - *9.2.* Review of the Aquatic Animals Commission's work plan for 2007-2008
10. **Date of the next meeting**

CHAPTER 1.1.1.

DEFINITIONS

Article 1.1.1.1.

Community position

The Community supports these proposals.

However the Community raises a concern on the definition of Stamping out policy: in certain circumstances, not all the animals killed for disease control purpose are to be destroyed by burning or burial, or by any other method that will eliminate the spread of the infection or infestation. In certain circumstances, these slaughtered animals may be intended for human consumption provided they do not show clinical signs of disease. To cover this possibility, we kindly suggest the OIE to add a final sentence to this definition as it is written in the Terrestrial Code. It would read:

Stamping-out policy
means the carrying out under the authority of the *Competent Authority*, on confirmation of a *disease*, of preventive aquatic animal health measures, consisting of killing the *aquatic animals* that are affected, those suspected of being affected in the *population* and those in other *populations* that have been exposed to *infection* or *infestation* by direct or indirect contact of a kind likely to cause the transmission of the *disease agent*. All these *aquatic animals*, vaccinated or unvaccinated, on an infected site should be killed and the carcasses destroyed by burning or burial, or by any other method that will eliminate the spread of *infection* or *infestation* through the carcasses or products of the *aquatic animals* destroyed.

The term modified stamping out policy should be used in communication to the OIE whenever the above animal health measures are not implemented in full and details of the modification should be given.

Aquatic animal health status
means the status of a country, *zone* or *compartment* with respect to an *aquatic animal disease*, according to the criteria listed in the relevant chapter of the *Aquatic Code* dealing with the *disease*.

Biosecurity plan
means a plan that identifies significant potential pathways for the introduction and spread of *disease* in a *zone* or *compartment*, and describe the measures which are being, or will be, applied to mitigate the risks to introduce and spread *disease* ~~risks~~, ~~in accordance with~~ taking into consideration the recommendations in the *Aquatic Code*. The plan should also describe~~s~~ how these measures are audited, with respect to both their implementation and their targeting, to ensure that the risks are regularly re-assessed and the measures adjusted accordingly.

Compartmentalisation
means identifying *compartments* for disease control or *international trade* purposes.

Disease
means clinical or non clinical *infection* or *infestation* with one or more of the aetiological agents of the diseases referred to in the *Aquatic Code*.

Infection
means the presence of a multiplying or otherwise developing or latent *disease agent* in ~~or, for ectoparasites, on~~ a host.

Infestation

means the presence in ~~large~~ sufficient numbers of a multiplying parasitic, or commensal, agent on a host so as to cause damage or *disease.*

Inspection

means the control carried out by the *Competent Authority* in order to ensure that an *aquatic animal* is/*aquatic animals* are free from the *diseases*~~/infections~~ considered in the *Aquatic Code*; the *inspection* may call for clinical examination, laboratory tests and, generally, the application of other procedures that could reveal an *infection* or *infestation* that may be present in an *aquatic animal population*.

Subpopulation

means a distinct part of a *population* identifiable according to specific common *aquatic animal* health characteristics.

Stamping-out policy

means the carrying out under the authority of the *Competent Authority*, on confirmation of a *disease*, of preventive aquatic animal health measures, consisting of killing the *aquatic animals* that are affected, those suspected of being affected in the *population* and those in other *populations* that have been exposed to *infection* or *infestation* by direct or indirect contact of a kind likely to cause the transmission of the *disease agent*. All these *aquatic animals*, vaccinated or unvaccinated, on an infected site should be killed and the carcasses destroyed by burning or burial, or by any other method that will eliminate the spread of *infection* or *infestation* through the carcasses or products of the *aquatic animals* destroyed.

Appendix III (contd)

This policy should be accompanied by cleansing and *disinfection* procedures as defined in the *Aquatic Code*. *Fallowing* should be for an appropriate period determined by *risk assessment*.

Subclinical

means without clinical manifestations, for example a stage of *infection* or *infestation* at which signs are not apparent or detectable by clinical examination.

Susceptible species

means a species of *aquatic animal* in which *infection* or *infestation* ~~by a disease~~ has been demonstrated by natural cases or by experimental exposure to the *disease agent* that mimics the natural pathways for *infection* or *infestation*. Each disease chapter in the *Aquatic Manual* contains a list of currently known *susceptible species*.

Targeted surveillance

means *surveillance* targeted at a specific *disease*~~, or~~ *infection* or *infestation*.

~~***Veterinary para-professional***~~

~~means a person who, for the purposes of the *Aquatic Code*, is authorised by the *veterinary statutory body* to carry out certain designated tasks (dependent upon the category of veterinary para-professional) in a country, and delegated to them under the responsibility and direction of a *veterinarian*. The tasks authorized for each category of *veterinary para-professional* should be defined by the *veterinary statutory body* depending on qualifications and training, and according to need.~~

Zoning

means identifying zones for disease control or international trade purposes.

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Appendix IV

CHAPTER 1.2.3.

DISEASES LISTED BY THE OIE

Community position

The Community supports this proposal.

Preamble: The following diseases are listed by the OIE according to the criteria for listing an aquatic animal disease (see Article 1.2.2.1.) or criteria for listing an emerging aquatic animal disease (see Article 1.2.2.2.)

Article 1.2.3.1.

The following diseases of fish are listed by the OIE:

- Epizootic haematopoietic necrosis
- Infectious haematopoietic necrosis
- Spring viraemia of carp
- Viral haemorrhagic septicaemia
- Infectious salmon anaemia
- Epizootic ulcerative syndrome
- Gyrodactylosis (*Gyrodactylus salaris*)
- Red sea bream iridoviral disease
- Koi herpesvirus disease.

Article 1.2.3.2.

The following diseases of molluscs are listed by the OIE:

- Infection with *Bonamia ostreae*
- Infection with *Bonamia exitiosa*
- Infection with *Marteilia refringens*
- Infection with *Perkinsus marinus*
- Infection with *Perkinsus olseni*
- Infection with *Xenohaliotis californiensis*.
- Abalone viral mortality (1).

Article 1.2.3.3.

The following diseases of crustaceans are listed by the OIE:

- Taura syndrome

Appendix IV (contd)

- White spot disease
- Yellowhead disease
- Tetrahedral baculovirosis (*Baculovirus penaei*)
- Spherical baculovirosis (*Penaeus monodon*-type baculovirus)
- Infectious hypodermal and haematopoietic necrosis
- Crayfish plague (*Aphanomyces astaci*)
- Necrotising hepatopancreatitis[2]
- Infectious myonecrosis[2]
- White tail disease [1]
- Hepatopancreatic parvovirus disease [1] 2
- Mourilyan virus disease [1] 2.

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[1] Listed according to Article 1.2.2.2.

[2] Listing of this disease is under study.

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—— text deleted

CHAPTER 1.4.4.

ZONING AND COMPARTMENTALISATION

Community position

The Community supports this proposal.

Article 1.4.4.1.

Introduction

Given the difficulty of establishing and maintaining freedom from a particular *disease* for an entire country ~~the status of *free country* for a particular *disease*~~, especially for *diseases* ~~the entry of which~~ whose entry is difficult to control ~~through measures at national boundaries~~, there may be benefits to one or more Member Countries in establishing and maintaining a *subpopulation* with a distinct *aquatic animal health status*. *Subpopulations* may be separated by natural or artificial geographical barriers or, in certain situations, by the application of appropriate management ~~systems~~ practices.

Zoning and *compartmentalisation* are procedures implemented by a country under the provisions of this chapter ~~with a view~~ to ~~defining~~ define *subpopulations* of distinct *aquatic animal health status* for the purpose of disease control or *international trade*. *Compartmentalisation* applies to a *subpopulation* when management practices related to biosecurity are the defining factors, while *zoning* applies when a *subpopulation* is defined on a geographical basis. In practice, spatial considerations and good management play important roles in the application of both concepts.

This chapter is to assist OIE Member Countries wishing to establish and maintain different *subpopulations*, using the principles of *compartmentalisation* and *zoning*. These principles should be applied in accordance with the measures recommended in the relevant *disease* chapter(s). This chapter also outlines a process through which trading partners may recognise such *subpopulations*. This process is best implemented by trading partners through establishing parameters and gaining agreement on the necessary measures prior to *outbreaks of disease*.

Before trade in *aquatic animals* or *aquatic animal products* may occur, an *importing country* needs to be satisfied that its *aquatic animal health status* will be appropriately protected. In most cases, the import regulations developed will rely in part on judgements made about the effectiveness of sanitary procedures undertaken by the *exporting country*, both at its borders and within its *territory*.

In addition to ~~As well as~~ contributing to the safety of *international trade*, *zoning* and *compartmentalisation* may assist *disease* control or eradication within Member Countries. *Zoning* may encourage the more efficient use of resources, and *compartmentalisation* may allow the functional separation of a *subpopulation* from other domestic or wild *aquatic animals* through biosecurity measures, which a *zone* (through geographical separation) would not achieve. Following an *outbreak of disease*, *compartmentalisation* may allow a Member Country be able to take advantage of epidemiological links among *subpopulations* or common practices relating to biosecurity, despite diverse geographical locations, to facilitate *disease* control and/or the resumption of trade.

Zoning and *compartmentalisation* may not be applicable to all *diseases*, but separate requirements will be developed for each *disease* for which the application of *zoning* or *compartmentalisation* is considered

appropriate.

To regain the status of a *free zone* or *free compartment* following an *outbreak of disease,* Member Countries should follow the recommendations in the relevant disease chapter in the *Aquatic Code*.

Appendix V (contd)

Article 1.4.4.2.

General considerations

The *Competent Authority* of an *exporting country* that is establishing a *zone* or *compartment* for *international trade* purposes should clearly define the *subpopulation* in accordance with the recommendations in the relevant chapters in the *Aquatic Code,* including those on *surveillance*, and the identification and traceability of *aquatic animals*. The *Competent Authority* of an *exporting country* should be able to explain to the *Competent Authority* of an *importing country* the basis for its claim of a distinct *aquatic animal health status* for the *zone* or *compartment* in such terms.

The procedures used to establish and maintain the distinct *aquatic animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances and will depend on the epidemiology of the *disease*, environmental factors, risk of introduction and establishment of *disease*, and applicable biosecurity measures. The *exporting country* should be able to demonstrate, through detailed documentation supplied to the *importing country*, published through official channels, that it has implemented the recommendations in the *Aquatic Code* for establishing and maintaining such a *zone* or *compartment*.

An *importing country* should recognise the existence of this *zone* or *compartment* when the appropriate measures recommended in the *Aquatic Code* are applied, and the *Competent Authority* of the *exporting country* certifies that this is the case. Note that an *importing country* may adopt a higher level of protection where it is scientifically justified and the obligations referred to in Article 1.4.1.2. are met. Article 1.4.4.4. is also relevant.

Where countries share a *zone* or *compartment*, the *Competent Authority* of each country should collaborate to define and fulfil their respective responsibilities.

~~Article 1.4.4.3.~~

~~**Prerequisite considerations in defining a zone or compartment**~~

The *exporting country* should conduct an assessment of the resources needed and available to establish and maintain a *zone* or *compartment* for *international trade* purposes. These include the human and financial resources and the technical capability of the *Competent Authority* (and of the relevant industry, in the case of a *compartment*) including on *disease surveillance* and *diagnosis*.

Article 1.4.4.43.

Principles for defining a zone or compartment

In conjunction with the above considerations and the definitions of *zone* and *compartment*, the following principles should apply when Member Countries define a *zone* or *compartment*:

1. The extent of a *zone* should be established by the *Competent Authority* on the basis of the definition of *zone* and made public through official channels.

2. The factors defining a *compartment* should be established by the *Competent Authority* on the basis of relevant criteria such as management and husbandry practices related to biosecurity, and made public through official channels.

3. *Aquatic animals* belonging to such *subpopulations* need to be recognizable as such through a clear epidemiological separation from other *aquatic animals* and all things presenting a *disease* risk.

4. For a *zone* or *compartment*, the *Competent Authority* should document in detail the measures taken to ensure the identification of the *subpopulation*, for example by means of registration of all the *aquaculture establishments* located in such a *zone* or *compartment* and the establishment and maintenance of its *aquatic animal health status* through a *biosecurity plan*. The measures used to establish and maintain the distinct *aquatic animal health status* of a *zone* or *compartment* should be appropriate to the particular circumstances and will depend on the epidemiology of the *disease*, environmental factors, the *aquatic animal health status* in adjacent areas, applicable biosecurity measures (including movement controls, use of natural and artificial boundaries, the spatial separation of *aquatic animals*, and commercial management and husbandry practices), and *surveillance*.

5. For a *compartment*, the *biosecurity plan* should describe the partnership between the relevant enterprise/industry and the *Competent Authority,* and their respective responsibilities, including the procedures for oversight of the operation of the *compartment* by the *Competent Authority*.

6. For a *compartment*, the *biosecurity plan* should also describe the routine operating procedures to provide clear evidence that the *surveillance* conducted and the management practices are adequate to meet the definition of the *compartment*. In addition to information on *aquatic animal* movements, the *biosecurity plan* should include production and stock records, feed sources, traceability, *surveillance* results, visitor logbook, morbidity and mortality history, medications, vaccinations, documentation of training and any other criteria necessary for evaluation of risk mitigation. The information required may vary according to the *aquatic animal* species and *disease(s)* under consideration. The *biosecurity plan* should also describe how the measures will be audited to ensure that the risks are regularly re-assessed and the measures adjusted accordingly.

7. Thus defined, the *zones* and *compartments* constitute the relevant *subpopulations* for the application of the recommendations in Part 2 of the *Aquatic Code*.

Article 1.4.4.~~5~~4.

Sequence of steps to be taken in ~~defining~~ establishing a zone/compartment and having it recognised for international trade purposes

There is no single sequence of steps which should be followed in ~~defining~~ establishing a *zone* or a *compartment*. The steps that the *Competent Authority* of the *importing country* and the *exporting country* choose and implement will generally depend on the circumstances existing within the countries and at their borders, and their trading history. The recommended steps are:

1. For zoning

   a) The *exporting country* identifies a geographical area, which it considers to contain an *aquatic animal subpopulation* with a distinct *aquatic animal health status* with respect to a specific *disease*/specific *diseases*, based on *surveillance*.

   b) The *exporting country* describes in the *biosecurity plan* for the *zone* the measures which are being, or will be, applied to distinguish such an area epidemiologically from other parts of its *territory*, in accordance with the recommendations in the *Aquatic Code*.

   c) The *exporting country* provides the above information to the *importing country*, with an explanation of why the area can be treated as an epidemiologically separated *zone* for *international trade* purposes.

   d) The *importing country* determines whether it accepts such an area as a *zone* for the importation of *aquatic animals* and *aquatic animal products*, taking into account:

i) an evaluation of the *exporting country*'s *Competent Authority*;

ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;

iii) its own *aquatic animal* health situation with respect to the *disease(s)* concerned; and

iv) other relevant OIE standards.

e) The *importing country* notifies the *exporting country* of the result of its determination and the underlying reasons, within a reasonable period of time, being either:

i) recognition of the *zone*;

ii) request for further information; or

iii) rejection of the area as a *zone* for *international trade* purposes.

f) An attempt should be made to resolve any differences over the ~~definition~~ recognition of the *zone*, either in the interim or finally, by using an agreed mechanism to reach consensus (such as the OIE dispute settlement mechanism).

g) The *importing country* and the *exporting country* ~~may~~ should enter into a formal agreement ~~defining~~ recognising the *zone*.

2. For compartmentalisation

a) Based on discussions with the relevant enterprise/industry, the *exporting country* identifies a *compartment* of one or more *aquaculture establishments* or other premises ~~owned by an enterprise(s) which~~ that operate~~s~~ under common management practices related to biosecurity, and which contains an identifiable *aquatic animal subpopulation* with a distinct *aquatic animal health status* with respect to a specific *disease*/specific *diseases*; the *exporting country* describes how this status is maintained through a partnership between the relevant enterprise/industry and the *Competent Authority* of the *exporting country*.

b) The *exporting country* examines the *compartment*'s *biosecurity plan* and confirms through an audit that:

i) the *compartment* is epidemiologically closed throughout its routine operating procedures as a result of effective implementation of its *biosecurity plan*; and

ii) the *surveillance* programme in place is appropriate to verify the status of such *aquaculture establishment(s)* with respect to such *disease(s)*.

c) The *exporting country* describes the *compartment*, in accordance with the recommendations in the *Aquatic Code*.

d) The *exporting country* provides the above information to the *importing country*, with an explanation of why such an enterprise can be treated as an epidemiologically separated *compartment* for *international trade* purposes.

e) The *importing country* determines whether it accepts such an enterprise as a *compartment* for the importation of *aquatic animals* and *aquatic animal products*, taking into account:

i) an evaluation of the *exporting country*'s *Competent Authority*;

ii) the result of a *risk assessment* based on the information provided by the *exporting country* and its own research;

iii) its own *aquatic animal* health situation with respect to the *disease(s)* concerned; and

iv) other relevant OIE standards.

f) The *importing country* notifies the *exporting country* of the result of its examination and the underlying reasons, within a reasonable period of time, being either:

i) recognition of the *compartment*;

ii) request for further information; or

iii) rejection of such an enterprise as a *compartment* for *international trade* purposes.

g) An attempt should be made to resolve any differences over the ~~definition~~ recognition of the *compartment*, either in the interim or finally, by using an agreed mechanism to reach consensus (such as the OIE dispute settlement mechanism).

h) The *importing country* and the *exporting country* ~~may~~ should enter into a formal agreement ~~definition~~ recognising the *compartment*.

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Appendix VI

CHAPTER 2.2.1.

INFECTION WITH *BONAMIA OSTREAE*

Community Position
The Community supports the proposed chapter.

However, the Community would like the OIE to take into account the following comments, when addressing future amendments to the Code

1) Article 2.2.1.3 (Commodities)

Point 1 a) ii). To our best knowledge, there is no scientific evidence that proves that larvae could be considered as safe commodities for directly-transmitted mollusc infections. Therefore , we would propose the non-inclusion of larvae in point 1 a) ii) of this article.

Point 1 c). To require packaging for direct retail sale for commodities such as off the shell (chilled or frozen) or half-shell (chilled) seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade".

An alternative solution would be to include those commodities in point 1.a).

2) Articles 2.2.1.4 and 2.2.1.5 (B. ostreae free country, zone or compartment)
Option 2 is irrelevant for freedom from B ostreae. According to our experience, a B. ostreae free country, zone or compartment cannot be declared free without a carefully planned targeted surveillance scheme.

3) Article 2.2.1.8. (Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Bonamia ostreae)*
The Community maintains its concern about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in this case the ICES guidelines) because of the lack of clarity of the validity of such external documents and any changes made to.

4) Article 2.2.1.10 and 2.2.1.11 (Importation of aquatic animal products)
It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.2.1.2, the Competent Authority of the importing country shall asses the risk and, if justified, apply risk mitigation measures. The importing country should be informed of the outcome of this assement and of the risk mitigation measures to be applied.
The article does not apply to commodities referred to in point 1 of Article 2.2.1.3.

Article 2.2.1.1.

For the purposes of the *Aquatic Code*, infection with *Bonamia ostreae* means *infection* only with *Bonamia ostreae*.

Methods for conducting surveillance, diagnosis and confirmatory identification of infection with *Bonamia ostreae* are provided in the *Aquatic Manual*.

Article 2.2.1.2.

Scope

The recommendations in this Chapter apply to: European flat oyster (*Ostrea edulis*), Australian mud oyster (*O. angasi*), Argentinean flat oyster (*O. puelchana*), Chilean flat oyster (*O. chilensis*), Asiatic oyster (*O. denselammellosa*) and Suminoe oyster (*Crassostrea ariakensis*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.2.1.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any *Bonamia ostreae* related conditions, regardless of the *Bonamia ostreae* status of the *exporting country*, *zone* or *compartment*:

   a) For the species referred to in Article 2.2.1.2. being used for any purpose:

      i) *commodities* treated in a manner that kills the host (and thereby inactivates the *disease agent*) e.g. ~~commercially~~ ~~sterile~~ canned or pasteurised products ~~or other heat treated~~;

      ii) ~~*gametes*, *eggs* and~~ larvae;

      iii) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent*.

   b) All *commodities* from *Crassostrea gigas*, *C. virginica*, *Ruditapes decussatus*, *R. philippinarum*, *Mytilus galloprovincialis* and *M. edulis*, including the live *aquatic animal*.

   c~~b~~) The following *commodities* destined for human consumption from the species referred to in Article 2.2.1.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

      ~~i) chemically preserved products (e.g. smoked, salted, pickled, marinated, etc.);~~

      ~~ii) non commercially sterile products (e.g. ready prepared meals) that have been heat treated in a manner to ensure the inactivation of the parasite;~~

      i~~i~~) off the shell (chilled or frozen) ~~packaged for direct retail trade~~;

      ii~~v~~) half-shell (chilled).

   ~~c) All *commodities* from *Crassostrea gigas*, *C. virginica*, *Ruditapes decussatus*, *R. philippinarum*, *Mytilus galloprovincialis* and *M. edulis*, including the live *aquatic animal*.~~

   For the *commodities* referred to in point 1~~b)~~c), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.2.1.2., other than *commodities* referred to in point 1 of Article 2.2.1.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.2.1.7. to 2.2.1.11. relevant to the *Bonamia ostreae* status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of infection with *Bonamia ostreae* of a *commodity* from bivalve species not ~~referred to~~ covered in Article 2.2.1.2. ~~(especially those of the genus *Ostrea*)~~ ~~n~~or in point 1~~c)~~b) of Article 2.2.1.3. but which could reasonably be expected to be a potential *Bonamia ostreae* vector ~~from an *exporting country*, *zone* or~~

~~*compartment* not declared free of *Bonamia ostreae*~~, the *Competent Authorities* should conduct a~~n~~ *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of *Bonamia ostreae*, and the potential consequences, associated with the importation of the *commodity* prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.2.1.4.

***Bonamia ostreae* free country**

A country may make a *self-declaration of freedom* from *Bonamia ostreae* if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *Bonamia ostreae* if all the areas covered by the shared water are declared *Bonamia ostreae* free *zones* (see Article 2.2.1.5.).

1. A country where none of the *susceptible species* referred to in Article 2.2.1.2. is present may make a *self-declaration of freedom* from *Bonamia ostreae* when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where any *susceptible species* referred to in Article 2.2.1.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.1. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Bonamia ostreae* when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years and infection with *Bonamia ostreae* is not known to be established in wild populations.

OR

3. A country where the last known clinical occurrence was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~, for example~~ (e.g. because of the absence of conditions conducive to clinical expression~~,~~ as described in Chapter 2.2.1. of the *Aquatic Manual*), may make a *self-declaration of freedom* from *Bonamia ostreae* when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.1. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Bonamia ostreae*.

OR

4. A country that has previously made a *self-declaration of freedom* from *Bonamia ostreae* but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from *Bonamia ostreae* again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.1. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Bonamia ostreae*; and

d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

In the meantime, part of the non-affected area may be declared a free *zone* provided that ~~it~~ such part meets the conditions in point 3 of Article 2.2.1.5.

Article 2.2.1.5.

***Bonamia ostreae* free zone or free compartment**

A *zone* or *compartment* free from *Bonamia ostreae* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Bonamia ostreae* and declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Bonamia ostreae* free *zone* or *compartment* if the conditions outlined below apply to all areas of the *zone* or *compartment*.

1. In a country of unknown status for *Bonamia ostreae*, a *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.2.1.2. is present may be declared free from *Bonamia ostreae* when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Bonamia ostreae*, a *zone* or *compartment* where any *susceptible species* referred to in Article 2.2.1.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.1. of the *Aquatic Manual*, may be declared free from *Bonamia ostreae* when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years and infection with *Bonamia ostreae* is not known to be established in wild populations.

OR

3. A *zone* or *compartment* where the last known clinical occurrence was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~, for example~~ (e.g. because of the absence of conditions conducive to clinical expression~~,~~ as described in Chapter 2.2.1. of the *Aquatic Manual*), may be declared free from *Bonamia ostreae* when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.1. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Bonamia ostreae*.

OR

4. A *zone* previously declared free from *Bonamia ostreae* but in which the *disease* is subsequently detected may ~~not~~ be declared free from *Bonamia ostreae* again ~~until~~ when the following conditions have been met:

a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.1. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Bonamia ostreae*; and

d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

Article 2.2.1.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *Bonamia ostreae* following the provisions of points 1 or 2 of Articles 2.2.1.4. or 2.2.1.5. (as relevant) may maintain its status as *Bonamia ostreae* free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *Bonamia ostreae* following the provisions of point 3 of Articles 2.2.1.4. or 2.2.1.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as *Bonamia ostreae* free provided that conditions that are conducive to clinical expression of infection with *Bonamia ostreae*, as described in Chapter 2.2.1. of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of infection with *Bonamia ostreae*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.2.1.7.

Importation of live aquatic animals from a country, zone or compartment declared free from *Bonamia ostreae*

When importing live *aquatic animals* of species referred to in Article 2.2.1.2. from a country, *zone* or *compartment* declared free from *Bonamia ostreae*, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.1.4. or 2.2.1.5. (as applicable), whether the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from *Bonamia ostreae*.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.2.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.1.3.

Article 2.2.1.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Bonamia ostreae*

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.2.1.2. from a country, zone or *compartment* not declared free from *Bonamia ostreae*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

   a) ~~1~~. the direct delivery ~~in~~to and lifelong holding of the consignment in biosecure ~~*quarantine*~~ facilities for~~;~~

   ~~2.~~ ~~the~~ continuous isolation ~~of the imported *aquatic animals*~~ from the local environment; and

   b) ~~3~~. the treatment of all effluent and waste material ~~from the processing~~ in a manner that ensures inactivation of *Bonamia ostreae*.

2. If the intention of the introduction is the establishment of a new stock, international standards, such as the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Code may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock health/disease history;

   c) take and test samples for *Bonamia ostreae*, pests and general health/disease status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *Bonamia ostreae* and perform general examinations for pests and general health/disease status;

   g) if *Bonamia ostreae* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as free of infection with *Bonamia ostreae* or specific pathogen free (SPF) for *Bonamia ostreae*;

   h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.1.3.

Article 2.2.1.9.

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from *Bonamia ostreae*

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.2.1.2. from a country, *zone* or *compartment* not declared free from *Bonamia ostreae*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment be delivered directly to and held in *quarantine* facilities until processing and/or consumption; and

2. all effluent and waste material from the processing be treated in a manner that ensures inactivation of *Bonamia ostreae*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.1.3.

Article 2.2.1.10.

Importation of aquatic animal products from a country, zone or compartment declared free from *Bonamia ostreae*

When importing *aquatic animal products* of species referred to in Article 2.2.1.2. from a country, *zone* or *compartment* declared free from *Bonamia ostreae*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.1.4. or 2.2.1.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Bonamia ostreae*.

The *certificate* should be in accordance with the Model Certificate in Appendix X.X.X. (under study).

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.1.3.

Article 2.2.1.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from *Bonamia ostreae*

When importing *aquatic animal products* of species referred to in Article 2.2.1.2. from a country, *zone* or *compartment* not declared free from *Bonamia ostreae*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.1.3.

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Appendix VII

CHAPTER 2.2.2.

INFECTION WITH *BONAMIA EXITIOSA*

Community Position
The Community supports the proposed chapter.

However, the Community would like the OIE to take into account the following comments, when addressing future amendments to the Code

1) Article 2.2.2.3 (Commodities)

Point 1 a) ii). To our best knowledge, there is no scientific evidence that proves that larvae could be considered as safe commodities for directly-transmitted mollusc infections. So, we would propose the non-inclusion of larvae in point 1 a)ii).

Point 1 c). To require packaging for direct retail sale for commodities such as off the shell (chilled or frozen) or half-shell (chilled) seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade"
An alternative solution would be to include those commodities in point 1.a).

2) Article 2.2.2.8. (Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Bonamia exitiosa*
The Community maintains its concern about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in this case the ICES guidelines) because of the lack of clarity of the validity of such external documents and any changes made to.

3) Article 2.2.2.10 and 2.2.2.11 (Importation of aquatic animal products)
It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.2.1.2, the Competent Authority of the importing country shall asses the risk and, if justified, apply risk mitigation measures. The importing country should be informed of the outcome of this assement and of the risk mitigation measures to be applied.
The article does not apply to commodities referred to in point 1 of Article 2.2.2.3.

Article 2.2.2.1.

For the purposes of the *Aquatic Code*, infection with *Bonamia exitiosa* means *infection* only with *Bonamia exitiosa*.

Methods for conducting surveillance, diagnosis and confirmatory identification of infection with *Bonamia exitiosa* are provided in the *Aquatic Manual*.

Article 2.2.2.2.

Scope

The recommendations in this Chapter apply to: Australian mud oyster (*Ostrea angasi*) and Chilean flat oyster (*O. chilensis*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.2.2.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any *Bonamia exitiosa* related conditions, regardless of the *Bonamia exitiosa* status of the *exporting country*, *zone* or *compartment*:

Appendix VII (contd)

a) For the species referred to in Article 2.2.2.2. being used for any purpose:

i) *commodities* treated in a manner that kills the host (and thereby inactivates the *disease agent*) e.g. ~~commercially~~ ~~sterile~~ canned or pasteurised products ~~or other heat treated products~~;

ii) ~~*gametes*, *eggs* and~~ larvae;

iii) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent*.

b) All *commodities* from *Crassostrea gigas* and *Saccostrea glomerata*, including the live *aquatic animal*.

c~~b~~) The following *commodities* destined for human consumption from the species referred to in Article 2.2.2.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

~~i) chemically preserved products (e.g. smoked, salted, pickled, marinated, etc.)~~;

~~ii) non-commercially sterile products (e.g. ready-prepared meals) that have been heat-treated in a manner to ensure the inactivation of the parasite~~;

i~~i~~) off the shell (chilled or frozen) ~~packaged for direct retail trade~~;

ii~~v~~) half-shell (chilled).

~~c) All *commodities* from *Crassostrea gigas*, *C. virginica* and *Saccostrea glomerata*, including the live *aquatic animal*.~~

For the *commodities* referred to in point 1~~b)~~c), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.2.2.2., other than *commodities* referred to in point 1 of Article 2.2.2.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.2.2.7. to 2.2.2.11. relevant to the *Bonamia exitiosa* status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of infection with *Bonamia exitiosa* of a *commodity* from bivalve species not covered in Article 2.2.2.2. ~~(especially those of the genus *Ostrea*)~~ ~~n~~or in point1~~c)~~b) of Article 2.2.2.3. but which could reasonably be expected to be a potential *Bonamia exitiosa* vector, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of *Bonamia exitiosa*, and the potential consequences, associated with the importation of the *commodity* prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.2.2.4.

***Bonamia exitiosa* free country**

A country may make a *self-declaration of freedom* from *Bonamia exitiosa* if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *Bonamia exitiosa* if all the areas covered by the shared water are declared *Bonamia exitiosa* free *zones* (see Article 2.2.2.5.).

1. A country where none of the *susceptible species* referred to in Article 2.2.2.2. is present may make a *self-declaration of freedom* from *Bonamia exitiosa* when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where any *susceptible species* referred to in Article 2.2.2.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.2. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Bonamia exitiosa* when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years and infection with *Bonamia exitiosa* is not known to be established in wild populations.

OR

3. A country where the last known clinical occurrence was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~,~~ ~~for example~~ (e.g. because of the absence of conditions conducive to clinical expression~~,~~ as described in Chapter 2.2.2. of the *Aquatic Manual*), may make a *self-declaration of freedom* from *Bonamia exitiosa* when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.2. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Bonamia exitiosa*.

OR

4. A country that has previously made a *self-declaration of freedom* from *Bonamia exitiosa* but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from *Bonamia exitiosa* again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.2. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Bonamia exitiosa*; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that ~~it~~ such part meets the conditions in point 3 of Article 2.2.2.5.

Article 2.2.2.5.

***Bonamia exitiosa* free zone or free compartment**

A *zone* or *compartment* free from *Bonamia exitiosa* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Bonamia exitiosa* and declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Bonamia exitiosa* free *zone* or *compartment* if the conditions outlined below apply to all areas of the *zone* or *compartment*.

1. In a country of unknown status for *Bonamia exitiosa*, a *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.2.2.2. is present may be declared free from *Bonamia exitiosa* when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Bonamia exitiosa*, a *zone* or *compartment* where any *susceptible species* referred to in Article 2.2.2.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.2. of the *Aquatic Manual*, may be declared free from *Bonamia exitiosa* when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years and infection with *Bonamia exitiosa* is not known to be established in wild populations.

OR

3. A *zone* or *compartment* where the last known clinical occurrence was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown, ~~for example~~ (e.g. because of the absence of conditions conducive to clinical expression, as described in Chapter 2.2.2. of the *Aquatic Manual*), may be declared free from *Bonamia exitiosa* when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.2. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Bonamia exitiosa*.

OR

4. A *zone* previously declared free from *Bonamia exitiosa* but in which the *disease* is subsequently detected may ~~not~~ be declared free from *Bonamia exitiosa* again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.2. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Bonamia exitiosa*; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

Article 2.2.2.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *Bonamia exitiosa* following the provisions of points 1 or 2 of Articles 2.2.2.4. or 2.2.2.5. (as relevant) may maintain its status as *Bonamia exitiosa* free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *Bonamia exitiosa* following the provisions of point 3 of Articles 2.2.2.4. or 2.2.2.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as *Bonamia exitiosa* free provided that conditions that are conducive to clinical expression of infection with *Bonamia exitiosa*, as described in Chapter 2.2.2. of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of infection with *Bonamia exitiosa*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.2.2.7.

Importation of live aquatic animals from a country, zone or compartment declared free from *Bonamia exitiosa*

When importing live *aquatic animals* of species referred to in Article 2.2.2.2. from a country, *zone* or *compartment* declared free from *Bonamia exitiosa*, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.2.4. or 2.2.2.5. (as applicable), whether the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from *Bonamia exitiosa*.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.2.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.2.3.

Article 2.2.2.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Bonamia exitiosa*

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.2.2.2. from a country, *zone* or *compartment* not declared free from *Bonamia exitiosa*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

   a) ~~1.~~ the direct delivery ~~in~~to and lifelong holding of the consignment in biosecure ~~*quarantine*~~ facilities for~~;~~

   ~~2.~~ ~~the~~ continuous isolation ~~of the imported *aquatic animals*~~ from the local environment; and

   b) ~~3.~~ the treatment of all effluent and waste material ~~from the processing~~ in a manner that ensures inactivation of *Bonamia exitiosa*.

2. If the intention of the introduction is the establishment of a new stock, international standards, such as the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Code may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

b) evaluate stock health/disease history;

c) take and test samples for *Bonamia exitiosa*, pests and general health/disease status;

d) import and quarantine in a secure facility a founder (F-0) population;

e) produce F-1 generation from the F-0 stock in *quarantine*;

f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *Bonamia exitiosa* and perform general examinations for pests and general health/disease status;

g) if *Bonamia exitiosa* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as free of infection with *Bonamia exitiosa* or specific pathogen free (SPF) for *Bonamia exitiosa*;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment.*

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.2.3.

Appendix VII (contd)

Article 2.2.2.9.

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from *Bonamia exitiosa*

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.2.2.2. from a country, *zone* or *compartment* not declared free from *Bonamia exitiosa*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment be delivered directly to and held in *quarantine* facilities until processing and/or consumption; and

2. all effluent and waste material from the processing be treated in a manner that ensures inactivation of *Bonamia exitiosa*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.2.3.

Article 2.2.2.10.

Importation of aquatic animal products from a country, zone or compartment declared free from *Bonamia exitiosa*

When importing *aquatic animal products* of species referred to in Article 2.2.2.2. from a country, *zone* or *compartment* declared free from *Bonamia exitiosa*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.2.4. or 2.2.2.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Bonamia exitiosa*.

The *certificate* should be in accordance with the Model Certificate in Appendix X.X.X. (under study).

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.2.3.

Article 2.2.2.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from *Bonamia exitiosa*

When importing *aquatic animal products* of species referred to in Article 2.2.2.2. from a country, *zone* or *compartment* not declared free from *Bonamia exitiosa*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.2.3.

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CHAPTER 2.2.3.

INFECTION WITH *HAPLOSPORIDIUM NELSONI*

Community Position
The Community supports the proposed chapter.

However, the Community would like the OIE to take into account the following comment, when addressing future amendments to the Code
1) Article 2.2.3.3 (Commodities)
Point 1 a) ii). To our best knowledge, there is no scientific evidence that proves that larvae could be considered as safe commodities. So, we would propose the non-inclusion of larvae in point 1 a) ii).
Point 1 c). To require packaging for direct retail sale for commodities such as off the shell (chilled or frozen) or half-shell (chilled) seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade"
An alternative solution would be to include those commodities in point 1.a).

2) Article 2.2.3.8. (Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Haplosporidium nelsoni)*
The Community maintains its concern about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in this case the ICES guidelines) because of the lack of clarity of the validity of such external documents and any changes made to.

3) Article 2.2.3.10 and 2.2.3.11 (Importation of aquatic animal products)
It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.2.3.2, the Competent Authority of the importing country shall asses the risk and, if justified, apply risk mitigation measures. The importing country should be informed of the outcome of this assement and of the risk mitigation measures to be applied.
The article does not apply to commodities referred to in point 1 of Article 2.2.3.3.

Article 2.2.3.1.

For the purposes of the *Aquatic Code*, infection with *Haplosporidium nelsoni* means *infection* only with *Haplosporidium nelsoni*.

Methods for conducting surveillance, diagnosis and confirmatory identification of infection with *Haplosporidium nelsoni* are provided in the *Aquatic Manual* (under study).

Article 2.2.3.2.

Scope

The recommendations in this Chapter apply to: Pacific oyster (*Crassostrea gigas*) and Eastern oyster (*C. virginica*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.2.3.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any *Haplosporidium nelsoni* related conditions, regardless of the *Haplosporidium nelsoni* status of the *exporting country*, *zone* or *compartment*:

   a) For the species referred to in Article 2.2.3.2. being used for any purpose:

      i) *commodities* treated in a manner that kills the host (and thereby inactivates the *disease agent*) e.g. ~~commercially~~ ~~sterile~~ canned or pasteurised products ~~or cooked products~~;

      ii) ~~*gametes*, *eggs* and~~ larvae;

      iii) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent*.

   b) All *commodities* from *Crassostrea ariakensis*, including the live *aquatic animal*.

   c~~b~~) The following *commodities* destined for human consumption from the species referred to in Article 2.2.3.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

      ~~i) chemically preserved products (e.g. smoked, salted, pickled, marinated, etc.);~~

      ~~ii) products (e.g. ready prepared meals) that have been heat treated in a manner to ensure the inactivation of the parasite;~~

      i~~i~~) off the shell (chilled or frozen) ~~packaged for direct retail trade~~;

      ii~~v~~) half-shell (chilled).

   ~~c) All *commodities* from *Crassostrea ariakensis*, including the live *aquatic animal*.~~

   For the *commodities* referred to in point 1~~b)~~c), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.2.3.2., other than *commodities* referred to in point 1 of Article 2.2.3.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.2.3.7. to 2.2.3.11. relevant to the *Haplosporidium nelsoni* status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of infection with *Haplosporidium nelsoni* of a *commodity* from bivalve species not covered in Article 2.2.3.2. ~~n~~or in point 1~~c)~~b) of Article 2.2.3.3. but which could reasonably be expected to be a potential *Haplosporidium nelsoni* vector, the *Competent Authorities* should conduct a~~n~~ *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of *Haplosporidium nelsoni*, and the potential consequences, associated with the importation of the *commodity* prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.2.3.4.

***Haplosporidium nelsoni* free country**

A country may make a *self-declaration of freedom* from *Haplosporidium nelsoni* if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from

Haplosporidium nelsoni if all the areas covered by the shared water are declared *Haplosporidium nelsoni* free *zones* (see Article 2.2.3.5.).

1. A country where none of the *susceptible species* referred to in Article 2.2.3.2. is present may make a *self-declaration of freedom* from *Haplosporidium nelsoni* when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where any *susceptible species* referred to in Article 2.2.3.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.3. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Haplosporidium nelsoni* when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years and infection with *Haplosporidium nelsoni* is not known to be established in wild populations.

OR

3. A country where the last known clinical occurrence was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~,~~ ~~for example~~ (e.g. because of the absence of conditions conducive to clinical expression~~,~~ as described in Chapter 2.2.3. of the *Aquatic Manual*), may make a *self-declaration of freedom* from *Haplosporidium nelsoni* when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.3. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Haplosporidium nelsoni*.

OR

4. A country that has previously made a *self-declaration of freedom* from *Haplosporidium nelsoni* but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from *Haplosporidium nelsoni* again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.3. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Haplosporidium nelsoni*; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that ~~it~~ such part meets the conditions in point 3 of Article 2.2.3.5.

Article 2.2.3.5.

Haplosporidium nelsoni **free zone or free compartment**

A *zone* or *compartment* free from *Haplosporidium nelsoni* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Haplosporidium nelsoni* and declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions

referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Haplosporidium nelsoni* free *zone* or *compartment* if the conditions outlined below apply to all areas of the *zone* or *compartment*.

1. In a country of unknown status for *Haplosporidium nelsoni*, a *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.2.3.2. is present may be declared free from *Haplosporidium nelsoni* when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Haplosporidium nelsoni*, a *zone* or *compartment* where any species referred to in Article 2.2.3.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.3. of the *Aquatic Manual*, may be declared free from *Haplosporidium nelsoni* when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years and infection with *Haplosporidium nelsoni* is not known to be established in wild populations.

OR

3. A *zone* or *compartment* where the last known clinical occurrence was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~;~~ ~~for example~~ (e.g. because of the absence of conditions conducive to clinical expression~~;~~ as described in Chapter 2.2.3. of the *Aquatic Manual*), may be declared free from *Haplosporidium nelsoni* when:

a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.3. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Haplosporidium nelsoni*.

OR

4. A *zone* previously declared free from *Haplosporidium nelsoni* but in which the *disease* is subsequently detected may ~~not~~ be declared free from *Haplosporidium nelsoni* again ~~until~~ when the following conditions have been met:

a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.3. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Haplosporidium nelsoni*; and

d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

Article 2.2.3.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *Haplosporidium nelsoni* following the provisions of points 1 or 2 of Articles 2.2.3.4. or 2.2.3.5. (as relevant) may maintain its status as *Haplosporidium nelsoni* free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *Haplosporidium nelsoni* following the provisions of point 3 of Articles 2.2.3.4. or 2.2.3.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as *Haplosporidium nelsoni* free provided that conditions that are conducive to clinical expression of infection with *Haplosporidium nelsoni*, as described in Chapter 2.2.3. of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of infection with *Haplosporidium nelsoni*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.2.3.7.

Importation of live aquatic animals from a country, zone or compartment declared free from *Haplosporidium nelsoni*

When importing live *aquatic animals* of species referred to in Article 2.2.3.2. from a country, *zone* or *compartment* declared free from *Haplosporidium nelsoni*, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.3.4. or 2.2.3.5. (as applicable), whether the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from *Haplosporidium nelsoni*.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.2.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.3.3.

Article 2.2.3.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Haplosporidium nelsoni*

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.2.3.2. from a country, *zone* or *compartment* not declared free from *Haplosporidium nelsoni*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

   a) ~~1.~~ the direct delivery ~~in~~to and lifelong holding of the consignment in biosecure ~~*quarantine*~~ facilities for;

   2. ~~the~~ continuous isolation ~~of the imported *aquatic animals*~~ from the local environment; and

   b) ~~3.~~ the treatment of all effluent and waste material ~~from the processing~~ in a manner that ensures inactivation of *Haplosporidium nelsoni*.

2. If the intention of the introduction is the establishment of a new stock, international standards, such as the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Code may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock health/disease history;

c) take and test samples for *Haplosporidium nelsoni*, pests and general health/disease status;

d) import and quarantine in a secure facility a founder (F-0) population;

e) produce F-1 generation from the F-0 stock in *quarantine*;

f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *Haplosporidium nelsoni* and perform general examinations for pests and general health/disease status;

g) if *Haplosporidium nelsoni* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as free of infection with *Haplosporidium nelsoni* or specific pathogen free (SPF) for *Haplosporidium nelsoni*;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.3.3.

Article 2.2.3.9.

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from *Haplosporidium nelsoni*

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.2.3.2. from a country, *zone* or *compartment* not declared free from *Haplosporidium nelsoni*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment be delivered directly to and held in *quarantine* facilities until processing and/or consumption; and

2. all effluent and waste material from the processing be treated in a manner that ensures inactivation of *Haplosporidium nelsoni*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.3.3.

Article 2.2.3.10.

Importation of aquatic animal products from a country, zone or compartment declared free from *Haplosporidium nelsoni*

When importing *aquatic animal products* of species referred to in Article 2.2.3.2. from a country, *zone* or *compartment* declared free from *Haplosporidium nelsoni*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.3.4. or 2.2.3.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Haplosporidium nelsoni*.

The *certificate* should be in accordance with the Model Certificate in Appendix X.X.X. (under study).

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.3.3.

Article 2.2.3.11.

Importation of aquatic animal products from a country, zone or compartment not declared free

from *Haplosporidium nelsoni*

When importing *aquatic animal products* of species referred to in Article 2.2.3.2. from a country, *zone* or *compartment* not declared free from *Haplosporidium nelsoni*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.3.3.

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CHAPTER 2.2.4.

INFECTION WITH *MARTEILIA REFRINGENS*

Community Position
The Community supports the proposed chapter.

However, the Community would like the OIE to take into account the following comments, when addressing future amendments to the Code.
1) Article 2.2.4.3 (Commodities)
Point 1 a) ii). To our best knowledge, there is no scientific evidence that proves that larvae could be considered as safe commodities. So, we would propose the non-inclusion of larvae in point 1 a) ii).
Point 1 c). To require packaging for direct retail sale for commodities such as off the shell (chilled or frozen) or half-shell (chilled) seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade"
An alternative solution would be to include those commodities in point 1.a).

2) Article 2.2.4.8. (Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Marteilia refringens)*
The Community maintains its concern about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in this case the ICES guidelines) because of the lack of clarity of the validity of such external documents and any changes made to.

3) Article 2.2.4.10 and 2.2.4.11 (Importation of aquatic animal products)
It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.2.4.2, the Competent Authority of the importing country shall asses the risk and, if justified, apply risk mitigation measures. The importing country should be informed of the outcome of this assement and of the risk mitigation measures to be applied.
The article does not apply to commodities referred to in point 1 of Article 2.2.4.3.

Article 2.2.4.1.

For the purposes of the *Aquatic Code*, infection with *Marteilia refringens* means *infection* only with *Marteilia refringens*.

Methods for conducting surveillance, diagnosis and confirmatory identification of infection with *Marteilia refringens* are provided in the *Aquatic Manual*.

Article 2.2.4.2.

Scope

The recommendations in this Chapter apply to: European flat oyster (*Ostrea edulis*), Australian mud oyster (*O. angasi*), Argentinean oyster (*O. puelchana*) and Chilean flat oyster (*O. chilensis*), ~~as well as~~ blue mussel (*Mytilus edulis*) and Mediterranean mussel (*M. galloprovincialis*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.2.4.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any *Marteilia refringens* related conditions, regardless of the *Marteilia refringens* status of the *exporting country*, *zone* or *compartment*:

   a) For the species referred to in Article 2.2.4.2. being used for any purpose:

      i) *commodities* treated in a manner that kills the host (and thereby inactivates the *disease agent*) e.g. ~~commercially~~ ~~sterile~~ canned or pasteurised products ~~or other heat treated products~~;

      ii) ~~*gametes*, *eggs* and~~ larvae;

      iii) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent.*

   b) All *commodities* from *Crassostrea gigas*, including the live *aquatic animal.*

   ~~c~~b) The following *commodities* destined for human consumption from the species referred to in Article 2.2.4.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

      ~~i) chemically preserved products (e.g. smoked, salted, pickled, marinated, etc.);~~

      ~~ii) non commercially sterile products (e.g. ready prepared meals) that have been heat treated in a manner to ensure the inactivation of the parasite;~~

      i~~i~~) off the shell (chilled or frozen) ~~packaged for direct retail trade~~;

      ii~~v~~) half-shell (chilled).

   ~~c) All *commodities* from *Crassostrea gigas*, including the live *aquatic animal.*~~

   For the *commodities* referred to in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.2.4.2., other than *commodities* referred to in point 1 of Article 2.2.4.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.2.4.7. to 2.2.4.11. relevant to the *Marteilia refringens* status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of infection with *Marteilia refringens* of a *commodity* from bivalve species not covered in Article 2.2.4.2. ~~(especially those the other species of the genera *Ostrea* and *Mytilus*)~~ ~~n~~or in point 1~~c~~b) of Article 2.2.4.3. but which could reasonably be expected to be a potential *Marteilia refringens* vector, the *Competent Authorities* should conduct a~~n~~ *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of *Haplosporidium nelsoni*, and the potential consequences, associated with the importation of the *commodity* prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.2.4.4.

***Marteilia refringens* free country**

A country may make a *self-declaration of freedom* from *Marteilia refringens* if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *Marteilia refringens* if all the areas covered by the shared water are declared *Marteilia refringens* free *zones* (see Article 2.2.4.5.).

1. A country where none of the *susceptible species* referred to in Article 2.2.4.2. is present may make a *self-declaration of freedom* from *Marteilia refringens* when *basic biosecurity conditions* have been continuously met

in the country for at least the past 3 years.

OR

2. A country where any *susceptible species* referred to in Article 2.2.4.2. is present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.4. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Marteilia refringens* when *basic biosecurity conditions* have been continuously met in the country for at least the past 3 years and infection with *Marteilia refringens* is not known to be established in wild populations.

OR

3. A country where the last known clinical occurrence was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown, for example (e.g. because of the absence of conditions conducive to clinical expression, as described in Chapter 2.2.4. of the *Aquatic Manual*), may make a *self-declaration of freedom* from *Marteilia refringens* when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 3 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.4. of the *Aquatic Manual*, has been in place for at least the last 2 of the past 3 years without detection of *Marteilia refringens*.

OR

4. A country that has previously made a *self-declaration of freedom* from *Marteilia refringens* but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from *Marteilia refringens* again until when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.4. of the *Aquatic Manual*, has been in place for at least the last 2 of the past 3 years without detection of *Marteilia refringens*; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 3 years.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that it such part meets the conditions in point 3 of Article 2.2.4.5.

Article 2.2.4.5.

Marteilia refringens **free zone or free compartment**

A *zone* or *compartment* free from *Marteilia refringens* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Marteilia refringens* and declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Marteilia refringens* free *zone* or *compartment* if the conditions outlined below apply to all areas of the *zone* or *compartment*.

1. In a country of unknown status for *Marteilia refringens*, a *zone* or *compartment* where none of the

susceptible species referred to in Article 2.2.4.2. is present may be declared free from *Marteilia refringens* when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 3 years.

OR

2. In a country of unknown status for *Marteilia refringens*, a *zone* or *compartment* where any *susceptible species* referred to in Article 2.2.4.2. is present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.4. of the *Aquatic Manual*, may be declared free from *Marteilia refringens* when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 3 years and infection with *Marteilia refringens* is not known to be established in wild populations.

OR

3. A *zone* or *compartment* where the last known clinical occurrence was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~, for example~~ (e.g. because of the absence of conditions conducive to clinical expression~~,~~ as described in Chapter 2.2.4. of the *Aquatic Manual*), may be declared free from *Marteilia refringens* when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 3 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.4. of the *Aquatic Manual*, has been in place for at least the last 2 of the past 3 years without detection of *Marteilia refringens*.

OR

4. A *zone* previously declared free from *Marteilia refringens* but in which the *disease* is subsequently detected may ~~not~~ be declared free from *Marteilia refringens* again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.4. of the *Aquatic Manual*, has been in place for at least the last 2 of the past 3 years without detection of *Marteilia refringens*; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 3 years.

Article 2.2.4.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *Marteilia refringens* following the provisions of points 1 or 2 of Articles 2.2.4.4. or 2.2.4.5. (as relevant) may maintain its status as *Marteilia refringens* free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *Marteilia refringens* following the provisions of point 3 of Articles 2.2.4.4. or 2.2.4.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as *Marteilia refringens* free provided that conditions that are conducive to clinical expression of infection with *Marteilia refringens*, as described in Chapter 2.2.4. of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of infection with *Marteilia refringens*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.2.4.7.

Importation of live aquatic animals from a country, zone or compartment declared free from *Marteilia refringens*

When importing live *aquatic animals* of species referred to in Article 2.2.4.2. from a country, *zone* or *compartment* declared free from *Marteilia refringens*, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.4.4. or 2.2.4.5. (as applicable), whether the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from *Marteilia refringens*.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.2.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.4.3.

Article 2.2.4.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Marteilia refringens*

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.2.4.2. from a country, *zone* or *compartment* not declared free from *Marteilia refringens*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

   a) ~~1.~~ the direct delivery ~~in~~to and lifelong holding of the consignment in biosecure ~~*quarantine*~~ facilities for;

   ~~2.~~ ~~the~~ continuous isolation ~~of the imported *aquatic animals*~~ from the local environment; and

   b) ~~3.~~ the treatment of all effluent and waste material ~~from the processing~~ in a manner that ensures inactivation of *Marteilia refringens*.

2. If the intention of the introduction is the establishment of a new stock, international standards, such as the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Code may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock health/disease history;

   c) take and test samples for *Marteilia refringens*, pests and general health/disease status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *Marteilia refringens* and perform general examinations for pests and general health/disease status;

   g) if *Marteilia refringens* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or

compartment, the F-1 stock may be defined as free of infection with *Marteilia refringens* or specific pathogen free (SPF) for *Marteilia refringens*;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.4.3.

Article 2.2.4.9.

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from *Marteilia refringens*

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.2.4.2. from a country, *zone* or *compartment* not declared free from *Marteilia refringens*, the *Competent Authority* of the *importing country* assess the *risk* and, if justified, require that:

Appendix IX (contd)

1. the consignment be delivered directly to and held in *quarantine* facilities until processing and/or consumption; and

2. all effluent and waste material from the processing be treated in a manner that ensures inactivation of *Marteilia refringens*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.4.3.

Article 2.2.4.10.

Importation of aquatic animal products from a country, zone or compartment declared free from *Marteilia refringens*

When importing *aquatic animal products* of species referred to in Article 2.2.4.2. from a country, *zone* or *compartment* declared free from *Marteilia refringens*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.4.4. or 2.2.4.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Marteilia refringens*.

The *certificate* should be in accordance with the Model Certificate in Appendix X.X.X. (under study).

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.4.3.

Article 2.2.4.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from *Marteilia refringens*

When importing *aquatic animal products* of species referred to in Article 2.2.4.2. from a country, *zone* or *compartment* not declared free from *Marteilia refringens*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.4.3.

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CHAPTER 2.2.5.

INFECTION WITH *MIKROCYTOS MACKINI*

Community Position
The Community supports the proposed chapter.

However, the Community would like the OIE to take into account the following comments, when addressing future amendments to the Code

1) Article 2.2.5.3 (Commodities)

Point 1 a) ii). To our best knowledge, there is no scientific evidence that proves that larvae could be considered as safe commodities for directly-transmitted mollusc infections. So, we would propose the non-inclusion of larvae in point 1 a)ii).

Point 1 c). To require packaging for direct retail sale for commodities such as off the shell (chilled or frozen) or half-shell (chilled) seems unjustified as these pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade"
An alternative solution would be to include those commodities in point 1.a).

2) Article 2.2.5.8. (Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Mikrocytos Mackini)*
The Community maintains its concern about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in this case the ICES guidelines) because of the lack of clarity of the validity of such external documents and any changes made to.

3) Article 2.2.5.10 and 2.2.5.11 (Importation of aquatic animal products)
It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.2.5.2, the Competent Authority of the importing country shall asses the risk and, if justified, apply risk mitigation measures. The importing country should be informed of the outcome of this assement and of the risk mitigation measures to be applied.
The article does not apply to commodities referred to in point 1 of Article 2.2.5.3.

Article 2.2.5.1.

For the purposes of the *Aquatic Code*, infection with *Mikrocytos mackini* means *infection* only with *Mikrocytos mackini*.

Methods for conducting surveillance, diagnosis and confirmatory identification of infection with *Mikrocytos mackini* are provided in the *Aquatic Manual* (under study).

Article 2.2.5.2.

Scope

The recommendations in this Chapter apply to: European flat oyster (*Ostrea edulis*), Olympia oyster (*O. conchaphila*), Pacific oyster (*Crassostrea gigas*) and Eastern oyster (*C. virginica*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.2.5.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any *Mikrocytos mackini* related conditions, regardless of the *Mikrocytos mackini* status of the *exporting country*, *zone* or *compartment*:

   a) For the species referred to in Article 2.2.5.2. being used for any purpose:

      i) *commodities* treated in a manner that kills the host (and thereby inactivates the *disease agent*) e.g. ~~commercially~~ ~~sterile~~ canned or pasteurised products ~~or other heat treated products~~;

      ii) ~~*gametes*, *eggs* and~~ larvae;

      iii) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent*.

   b) All *commodities* from *Panope abrupta*, including the live *aquatic animal*.

   c~~b~~) The following *commodities* destined for human consumption from the species referred to in Article 2.2.5.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

      ~~i)~~ ~~chemically preserved products (e.g. smoked, salted, pickled, marinated, etc.);~~

      ~~ii)~~ ~~non commercially sterile products (e.g. ready prepared meals) that have been heat treated in a manner to ensure the inactivation of the parasite;~~

      ~~i~~i) off the shell (chilled or frozen) ~~packaged for direct retail trade~~.

   ~~c)~~ ~~All *commodities* from *Panope abrupta*, including the live *aquatic animal*.~~

   For the *commodities* referred to in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.2.5.2., other than *commodities* referred to in point 1 of Article 2.2.5.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.2.5.7. to 2.2.5.11. relevant to the *Mikrocytos mackini* status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of infection with *Mikrocytos mackini* of a *commodity* from bivalve species not covered in Article 2.2.5.2. ~~n~~or in point 1~~c~~)b) of Article 2.2.5.3. but which could reasonably be expected to be a potential *Mikrocytos mackini* vector, the *Competent Authorities* should conduct a~~n~~ *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of *Haplosporidium nelsoni*, and the potential consequences, associated with the importation of the *commodity* prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.2.5.4.

***Mikrocytos mackini* free country**

A country may make a *self-declaration of freedom* from *Mikrocytos mackini* if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *Mikrocytos mackini* if all the areas covered by the shared water are declared *Mikrocytos mackini* free *zones* (see Article 2.2.5.5.).

1. A country where none of the *susceptible species* referred to in Article 2.2.5.2. is present may make a *self-declaration of freedom* from *Mikrocytos mackini* when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where any *susceptible species* referred to in Article 2.2.5.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.5. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Mikrocytos mackini* when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years and infection with *Mikrocytos mackini* is not known to be established in wild populations.

OR

3. A country where the last known clinical occurrence was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown, ~~for example~~ (e.g. because of the absence of conditions conducive to clinical expression, as described in Chapter 2.2.5. of the *Aquatic Manual*), may make a *self-declaration of freedom* from *Mikrocytos mackini* when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.5. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Mikrocytos mackini*.

OR

4. A country that has previously made a *self-declaration of freedom* from *Mikrocytos mackini* but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from *Mikrocytos mackini* again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.5. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Mikrocytos mackini*; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that ~~it~~ such part meets the conditions in point 3 of Article 2.2.5.5.

Article 2.2.5.5.

***Mikrocytos mackini* free zone or free compartment**

A *zone* or *compartment* free from *Mikrocytos mackini* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Mikrocytos mackini* and declared free by the *Competent Authority(ies)* of the country(ies) concerned, if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Mikrocytos mackini* free *zone* or *compartment* if the conditions outlined below apply to all areas of the *zone* or *compartment*.

1. In a country of unknown status for *Mikrocytos mackini*, a *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.2.5.2. is present may be declared free from *Mikrocytos mackini*

when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. In a country of unknown status for *Mikrocytos mackini*, a *zone* or *compartment* where any *susceptible species* referred to in Article 2.2.5.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.5. of the *Aquatic Manual*, may be declared free from *Mikrocytos mackini* when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years and infection with *Mikrocytos mackini* is not known to be established in wild populations.

OR

3. A *zone* or *compartment* where the last known clinical occurrence was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~,~~ ~~for example~~ (e.g. because of the absence of conditions conducive to clinical expression~~,~~ as described in Chapter 2.2.5. of the *Aquatic Manual*), may be declared free from *Mikrocytos mackini* when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.5. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Mikrocytos mackini*.

OR

4. A *zone* previously declared free from *Mikrocytos mackini* but in which the *disease* is subsequently detected may ~~not~~ be declared free from *Mikrocytos mackini* again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.5. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Mikrocytos mackini*; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

Article 2.2.5.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *Mikrocytos mackini* following the provisions of points 1 or 2 of Articles 2.2.5.4. or 2.2.5.5. (as relevant) may maintain its status as *Mikrocytos mackini* free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *Mikrocytos mackini* following the provisions of point 3 of Articles 2.2.5.4. or 2.2.5.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as *Mikrocytos mackini* free provided that conditions that are conducive to clinical expression of infection with *Mikrocytos mackini*, as described in Chapter 2.2.5. of the *Aquatic Manual*, exist and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of infection with *Mikrocytos mackini*, *targeted surveillance* needs to be

continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.2.5.7.

Importation of live aquatic animals from a country, zone or compartment declared free from *Mikrocytos mackini*

When importing live *aquatic animals* of species referred to in Article 2.2.5.2. from a country, *zone* or *compartment* declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.5.4. or 2.2.5.5. (as applicable), whether the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from *Mikrocytos mackini*.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.2.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.5.3.

Article 2.2.5.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Mikrocytos mackini*

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.2.5.2. from a country, *zone* or *compartment* not declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

   a) ~~1.~~ the direct delivery ~~in~~to and lifelong holding of the consignment in biosecure ~~*quarantine*~~ facilities for;

   ~~2.~~ ~~the~~ continuous isolation ~~of the imported *aquatic animals*~~ from the local environment; and

   b) ~~3.~~ the treatment of all effluent and waste material ~~from the processing~~ in a manner that ensures inactivation of *Mikrocytos mackini*.

2. If the intention of the introduction is the establishment of a new stock, international standards, such as the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Code may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock health/disease history;

   c) take and test samples for *Mikrocytos mackini*, pests and general health/disease status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *Mikrocytos mackini* and perform general examinations for pests and general health/disease status;

   g) if *Mikrocytos mackini* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or

compartment, the F-1 stock may be defined as free of infection with *Mikrocytos mackini* or specific pathogen free (SPF) for *Mikrocytos mackini*;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.5.3.

Article 2.2.5.9.

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from *Mikrocytos mackini*

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.2.5.2. from a country, *zone* or *compartment* not declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

Appendix X (contd)

1. the consignment be delivered directly to and held in *quarantine* facilities until processing and/or consumption; and

2. all effluent and waste material from the processing be treated in a manner that ensures inactivation of *Mikrocytos mackini*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.5.3.

Article 2.2.5.10.

Importation of aquatic animal products from a country, zone or compartment declared free from *Mikrocytos mackini*

When importing *aquatic animal products* of species referred to in Article 2.2.5.2. from a country, *zone* or *compartment* declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.5.4. or 2.2.5.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Mikrocytos mackini*.

The *certificate* should be in accordance with the Model Certificate in Appendix X.X.X. (under study).

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.5.3.

Article 2.2.5.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from *Mikrocytos mackini*

When importing *aquatic animal products* of species referred to in Article 2.2.5.2. from a country, *zone* or *compartment* not declared free from *Mikrocytos mackini*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.5.3.

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CHAPTER 2.2.8.

INFECTION WITH *XENOHALIOTIS CALIFORNIENSIS*

Community Position
The Community supports the proposed chapter.

However, the Community would like the OIE to take into account the following comments, when addressing future amendments to the Code
1) Article 2.2.8.3 (Commodities)
Point 1 a) ii). To our best knowledge, there is no scientific evidence that proves that larvae could be considered as safe commodities. So, we would propose the non-inclusion of larvae in point 1 a) ii).
Point 1 c). To require packaging for direct retail sale for commodities such as off the shell or eviscerated abalone (chilled or frozen) seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade"
An alternative solution would be to include those commodities in point 1.a).

2) Article 2.2.2.8. (Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Xenohaliotis californiensis)*
The Community maintains its concern about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in this case the ICES guidelines) because of the lack of clarity of the validity of such external documents and any changes made to.

3) Article 2.2.8.10 and 2.2.8.11 (Importation of aquatic animal products)
It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.2.8.2, the Competent Authority of the importing country shall asses the risk and, if justified, apply risk mitigation measures. The importing country should be informed of the outcome of this assement and of the risk mitigation measures to be applied.
The article does not apply to commodities referred to in point 1 of Article 2.2.8.3.

Article 2.2.8.1.

For the purposes of the *Aquatic Code*, infection with *Xenohaliotis californiensis* means *infection* only with *Xenohaliotis californiensis*.

Methods for conducting surveillance, diagnosis and confirmatory identification of infection with *Xenohaliotis californiensis* are provided in the *Aquatic Manual*.

Article 2.2.8.2.

Scope

The recommendations in this Chapter apply to: black abalone (*Haliotis cracherodii*), white abalone (*H. sorenseni*), red abalone (*H. rufescens*), pink abalone (*H. corrugata*), green abalone (*H. tuberculata* and *H. fulgens*), flat abalone (*H. wallalensis*) and Japanese abalone (*H. discus-hannai*). These recommendations also

apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.2.8.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any *Xenohaliotis californiensis* related conditions, regardless of the *Xenohaliotis californiensis* status of the *exporting country*, *zone* or *compartment*:

   a) For the species referred to in Article 2.2.8.2. being used for any purpose:

      i) *commodities* treated in a manner that kills the host (and thereby inactivates the *disease agent*) e.g. ~~commercially~~ ~~sterile~~ canned or pasteurised products ~~or other heat treated products~~;

      ii) *gametes*, *eggs* and larvae;

      iii) shells;

      iv) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent*.

   b) The following *commodities* destined for human consumption from the species referred to in Article 2.2.8.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

      ~~i) chemically preserved products (e.g. smoked, salted, pickled, marinated, etc.);~~

      ~~ii) non commercially sterile products (e.g. ready prepared meals) that have been heat treated in a manner to ensure the inactivation of the bacterium parasite;~~

      ~~i~~i) off the shell, eviscerated abalone (chilled or frozen) ~~packaged for direct retail trade~~.

   For the *commodities* referred to in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of *commodities* of a species referred to in Article 2.2.8.2., other than *commodities* referred to in point 1 of Article 2.2.8.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.2.8.7. to 2.2.8.11. relevant to the *Xenohaliotis californiensis* status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of infection with *Xenohaliotis californiensis* of a *commodity* from mollusc species not covered in Article 2.2.8.2. ~~(especially those of the genus *Haliotis*)~~ but which could reasonably be expected to be a potential *Xenohaliotis californiensis* vector, the *Competent Authorities* should conduct a~~n~~ *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of *Haplosporidium nelsoni*, and the potential consequences, associated with the importation of the *commodity* prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.2.8.4.

***Xenohaliotis californiensis* free country**

A country may make a *self-declaration of freedom* from *Xenohaliotis californiensis* if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from *Xenohaliotis californiensis* if all the areas covered by the shared water are declared *Xenohaliotis californiensis* free *zones* (see Article 2.2.8.5.).

1. A country where none of the *susceptible species* referred to in Article 2.2.8.2. is present may make a *self-*

declaration of freedom from *Xenohaliotis californiensis* when *basic biosecurity conditions* have been continuously met in the country for at least the past 3 ~~2~~ years.

OR

2. A country where any *susceptible species* referred to in Article 2.2.8.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.8. of the *Aquatic Manual*, may make a *self-declaration of freedom* from *Xenohaliotis californiensis* when *basic biosecurity conditions* have been continuously met in the country for at least the past 3 ~~2~~ years and infection with *Xenohaliotis californiensis* is not known to be established in wild populations.

OR

3. A country where the last known clinical occurrence was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~, for example~~ (e.g. because of the absence of conditions conducive to clinical expression~~,~~ as described in Chapter 2.2.8. of the *Aquatic Manual*), may make a *self-declaration of freedom* from *Xenohaliotis californiensis* when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 3 ~~2~~ years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.8. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Xenohaliotis californiensis*.

OR

4. A country that has previously made a *self-declaration of freedom* from *Xenohaliotis californiensis* but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from *Xenohaliotis californiensis* again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.8. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Xenohaliotis californiensis*; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 3 years.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that ~~it~~ such part meets the conditions in point 3 of Article 2.2.8.5.

Article 2.2.8.5.

***Xenohaliotis californiensis* free zone or free compartment**

A *zone* or *compartment* free from *Xenohaliotis californiensis* may be established within the *territory* of one or more countries of infected or unknown status for infection with *Xenohaliotis californiensis* and declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a *Xenohaliotis californiensis* free *zone* or *compartment* if the conditions outlined below apply to all areas of the *zone* or

compartment.

1. In a country of unknown status for *Xenohaliotis californiensis*, a *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.2.8.2. is present may be declared free from *Xenohaliotis californiensis* when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 3 ~~2~~ years.

OR

2. In a country of unknown status for *Xenohaliotis californiensis*, a *zone* or *compartment* where any *susceptible species* referred to in Article 2.2.8.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions – in all areas where the species are present – that are conducive to its clinical expression, as described in Chapter 2.2.8. of the *Aquatic Manual*, may be declared free from *Xenohaliotis californiensis* when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 3 ~~2~~ years and infection with *Xenohaliotis californiensis* is not known to be established in wild populations.

OR

3. A *zone* or *compartment* where the last known clinical occurrence was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~, for example~~ (e.g. because of the absence of conditions conducive to clinical expression~~,~~ as described in Chapter 2.2.8. of the *Aquatic Manual*), may be declared free from *Xenohaliotis californiensis* when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 3 ~~2~~ years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.8. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Xenohaliotis californiensis*.

OR

4. A *zone* previously declared free from *Xenohaliotis californiensis* but in which the *disease* is subsequently detected may ~~not~~ be declared free from *Xenohaliotis californiensis* again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.2.8. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *Xenohaliotis californiensis*; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 3 years.

Article 2.2.8.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from *Xenohaliotis californiensis* following the provisions of points 1 or 2 of Articles 2.2.8.4. or 2.2.8.5. (as relevant) may maintain its status as *Xenohaliotis californiensis* free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from *Xenohaliotis californiensis* following the provisions of point 3 of Articles 2.2.8.4. or 2.2.8.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as *Xenohaliotis californiensis* free provided that conditions that are conducive to clinical expression of infection with *Xenohaliotis californiensis*, as described in Chapter 2.2.8. of the *Aquatic Manual*, exist and *basic*

biosecurity conditions are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of infection with *Xenohaliotis californiensis*, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.2.8.7.

Importation of live aquatic animals from a country, zone or compartment declared free from *Xenohaliotis californiensis*

When importing live *aquatic animals* of species referred to in Article 2.2.8.2. from a country, *zone* or *compartment* declared free from *Xenohaliotis californiensis*, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.8.4. or 2.2.8.5. (as applicable), whether the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from *Xenohaliotis californiensis*.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.2.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.8.3.

Article 2.2.8.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Xenohaliotis californiensis*

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.2.8.2. from a country, *zone* or *compartment* not declared free from *Xenohaliotis californiensis*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

   a) ~~1.~~ the direct delivery ~~in~~to and lifelong holding of the consignment in biosecure ~~*quarantine*~~ facilities for;

   ~~2.~~ ~~the~~ continuous isolation ~~of the imported *aquatic animals*~~ from the local environment; and

   b) ~~3.~~ the treatment of all effluent and waste material ~~from the processing~~ in a manner that ensures inactivation of *Xenohaliotis californiensis*.

2. If the intention of the introduction is the establishment of a new stock, international standards, such as the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Code may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock health/disease history;

   c) take and test samples for *Xenohaliotis californiensis*, pests and general health/disease status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *Xenohaliotis californiensis* and perform general examinations for pests and general health/disease status;

g) if *Xenohaliotis californiensis* is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as free of infection with *Xenohaliotis californiensis* or specific pathogen free (SPF) for *Xenohaliotis californiensis*;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.8.3.

Article 2.2.8.9.

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from *Xenohaliotis californiensis*

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.2.8.2. from a country, *zone* or *compartment* not declared free from *Xenohaliotis californiensis*, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment be delivered directly to and held in *quarantine* facilities until processing and/or consumption; and

2. all effluent and waste material from the processing be treated in a manner that ensures inactivation of *Xenohaliotis californiensis*.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.8.3.

Article 2.2.8.10.

Importation of aquatic animal products from a country, zone or compartment declared free from *Xenohaliotis californiensis*

When importing *aquatic animal products* of species referred to in Article 2.2.8.2. from a country, *zone* or *compartment* declared free from *Xenohaliotis californiensis*, the *Competent Authority* of the *importing country* should require that the consignment be accompanied by an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country*.

This *certificate* must certify, on the basis of the procedures described in Articles 2.2.8.4. or 2.2.8.5. (as applicable), whether or not the place of production of the consignment is a country, *zone* or *compartment* declared free from *Xenohaliotis californiensis*.

The *certificate* should be in accordance with the Model Certificate in Appendix X.X.X. (under study).

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.8.3.

Article 2.2.8.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from *Xenohaliotis californiensis*

When importing *aquatic animal products* of species referred to in Article 2.2.8.2. from a country, *zone* or *compartment* not declared free from *Xenohaliotis californiensis*, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* referred to in point 1 of Article 2.2.8.3.

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CHAPTER 1.5.1.

RECOMMENDATIONS FOR TRANSPORT

Community Position
The Community supports the proposed chapter.

However, the Community would like the OIE to take into account the following comments, when addressing future amendments to the Code:
1) Article 1.5.1.4 (Disinfection and other sanitary measures)
The references to the Competent Authority (point 2 and 3 of the article) need to clarify who the the Competent Authority concernes is, e.g. the Competent Authority of the exporting country or the Competent Authority of the importing country.

2) Article 1.5.1.5 (Treatment of transportation water)
The text of this article does not reflect the actual characteristics of the transport of aquatic animals by sea.

If the transport water cannot be replaced during the transport, it will imply that all the travels should be done with closed valves. This approach seems unrealistic and with detrimental welfare implications. Therefore, in case of sea transport, we propose to allow the water exchange following a risk analysis taking into account some factors such as the proximity to fish farms or wild fisheries. As well, there is no need to establish designated sites to carry out the total water replacement. It would be better to define in which areas the replacement cannot be done taking into consideration the same factors.

The compulsory requirement to disinfect the transport water does not fit with the sea-transport as it is not always necessary.

3) Article 1.5.1.6 (Discharge of infected material)

The same comments are applicable to this article.

.Article 1.5.1.1.

General arrangements

1. These arrangements should be compulsory in all countries either by legislative or regulatory texts and methods of application should be described in a manual available to all concerned.

2. *Vehicles* (or *containers*) used for the *transport* of *aquatic animals* shall be designed, constructed and fitted in such a way as to withstand the weight of the *aquatic animals* and water and to ensure their safety and welfare during *transportation*. *Vehicles* shall be thoroughly cleansed and disinfected before use according to the guidelines given in the *Aquatic Code*.

3. *Vehicles* (or *containers*) in which *aquatic animals* are confined during *transport* by sea or by air shall be secured to maintain optimal conditions for the *aquatic animals* during *transport*, and to allow easy access by the attendant.

Article 1.5.1.2.

Particular arrangements for containers

1. The construction of *containers* intended for *transportation* of *aquatic animals* shall be such that the accidental release of water, etc., is prevented during *transport*.

2. In the case of the *transportation* of *aquatic animals*, provision shall be made to enable preliminary observation of the contents of *containers*.

3. *Containers* in transit in which there are *aquatic animal products* shall not be opened unless the *Competent Authorities* of the *transit country* consider it necessary. If this is the case, *containers* shall be subject to precautions ~~taken~~ to ~~avoid any *risk* of~~ prevent contamination.

4. *Containers* shall be loaded only with one kind of product or, at least, with products not susceptible to contamination by one another.

5. It rests with each country to decide on the facilities it requires for the *transport* and importation of *aquatic animals* and *aquatic animal products* in *containers*.

Appendix XII (contd)

Article 1.5.1.3.

Particular arrangements for the transport of aquatic animals by air

1. The stocking densities for the *transport* of *aquatic animals* ~~in aircraft~~ or *containers* should be determined by taking the following into consideration when transporting by air:

   a) the total ~~cubic metres~~ volume of available space for each type of *aquatic animal*;

   b) the oxygenation capacity ~~of the equipment attached to the aircraft and~~ available to supply the *containers* while on the ground and during all stages of the flight.

   With regard to fish, molluscs and crustaceans, the space reserved for each *aquatic animal* species in ~~the aircraft or~~ *containers* that have been fitted for the separate *transportation* of several *aquatic animals* or for the *transportation* of groups of *aquatic animals* should comply with acceptable densities specified for the species in question.

2. The OIE-approved International Air Transport Association (IATA) Regulations for live animals ~~(which are approved by the OIE)~~ may be adopted if they do not conflict with national legislative arrangements. (Copies of these Regulations are obtainable from the International Air Transport Association, 800 Place Victoria, P.O. Box 113, Montreal, Quebec H4Z 1M1, Canada.)

Article 1.5.1.4.

Disinfection and other sanitary measures

1. *Disinfection* and all zoo-sanitary work should be carried out in order to:

   a) avoid all unjustified inconvenience and to prevent damage or injury to the health of people and *aquatic animals*;

   b) avoid damage to the structure of the *vehicle* or its appliances;

   c) prevent, as far as possible, any damage to *aquatic animal products*~~, fish *eggs* as well as molluse and~~

~~crustacean larvae~~.

2. On request, the *Competent Authority* shall issue the transporters with a certificate indicating the measures that have been applied to all *vehicles*, the parts of the *vehicle* that have been treated, the methods used and the reasons that led to the application of the measures.

   In the case of aircraft, the certificate may be replaced, on request, by an entry in the General Declaration of the aircraft.

3. Likewise, the *Competent Authority* shall issue on request:

   a) a certificate showing the date of arrival and departure of the *aquatic animals*;

   b) a certificate to the shipper or exporter, the consignee and transporter or their representatives, indicating the measures applied.

Article 1.5.1.5.

~~**Transportation water**~~

~~Water to be used for *transportation* of *aquatic animals* should be appropriately treated in order to minimise the risk of transferring pathogens. The specific recommendations are provided in the Chapter on "Disinfection" of the *Aquatic Code*.~~

~~Article 1.5.1.56.~~

Treatment of transportation water

Water to be used for *transportation* of *aquatic animals* should be appropriately treated after transport and/or before discharge in order to minimise the risk of transferring pathogens. The specific recommendations are provided in the Chapter of the *Aquatic Code* on Disinfection.

During *transportation* of *aquatic animals*, the transporter should not be permitted to evacuate and replace the water in the *transport* tanks except on specifically designated sites in the national *territory*. The waste and rinsing water should not be emptied into a drainage system that is directly connected to an aquatic environment where *aquatic animals* are present. The water from the tanks should therefore either be disinfected by a recognised process (for example, 50 mg iodine or chlorine/litre for one hour), or sprayed over land that does not directly drain into waters containing *aquatic animals*. Each country shall designate the sites in their national *territories* where these operations can be carried out.

Article 1.5.1.6.

Discharge of infected material

The *Competent Authority* shall take all practical measures to prevent the discharge of any infective material, including transport water, into internal or territorial waters.

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Appendix XIII

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CHAPTER 2.1.17.

KOI HERPESVIRUS DISEASE

Community Position
The Community supports the proposed chapter.

However, the Community would like the OIE to take into account the following comments, when addressing future amendments to the Code

1) Article 2.1.17.3. (Commodities)
Point 1 c). To require packaging for direct retail sale for commodities such as evicerated fish, fillets or cutlets (chilled or frozen or dried *eviscerated fish* (including air dried, flame dried and sun dried). seems unjustified as these pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade"
An alternative solution would be to include those commodities in point 1.a).

2) Articles 2.1.17.4 and 2.1.17.5. (Koi herpes virus disease free country, zone or compartment)
The Community would ask the OIE to align the 25 years period needed to obtain the freedom status for historical reasons (point 2 in both articles) with the 10 years period for the same purposes proposed in the mollusc and crustacean chapters. The Community would propose 10 years in all chapters. Moreover, suitable KHVD diagnostic methods are relatively new. Therefore, no country could comply with this 25 year period for a long period of time, making this requirement too stringent.

3) Article 2.1.17.8. (Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from*Koi herpes virus disease)*
The Community maintains its concern about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in this case the ICES guidelines) because of the lack of clarity of the validity of such external documents and any changes made to.

4) Article 2.1.17.12 (Importation of aquatic animal products from a country, zone or compartment not declared free from koi herpes virus disease).
In the case of eviscerated fish the Community considers it unjustifiable to require heavy risk mitigation measures. Thus, we would ask the OIE to delete the reference to "eviscerated fish" from the second paragraph of this article.The second paragraph would read:
In the case of dead, **uneviscerated** *aquatic animals*,(**delete: whether *eviscerated* or uneviscerated**,) such risk mitigation measures may include:

1. the direct delivery into and holding of the consignment in biosecure/*quarantine* facilities for processing to one of the products referred to in point 1 of Article 2.1.17.3. or other products authorised by the *Competent Authority*;

2. the treatment of all effluent and waste materials in a manner that ensures inactivation of koi herpesvirus.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.17.3.

5) Article 2.1.17.11 and 2.1.17.12 (Importation of aquatic animal products).
It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products

When importing *aquatic animal products* of species referred to in article 2.1.17.2, the Competent Authority of the importing country shall asses the risk and, if justified, apply risk mitigation measures. The importing country should be informed of the outcome of this assement and of the risk mitigation measures to be applied.

The article does not apply to commodities referred to in point 1 of Article 2.1.17.3.

Article 2.1.17.1.

For the purposes of the *Aquatic Code*, koi herpesvirus disease (KHVD) means *infection* with the viral species koi herpesvirus (KHV) tentatively placed in the sub-family *Cyprinid herpesvirus* of the family Herpesviridae.

Methods for conducting surveillance and diagnosis of koi herpesvirus disease are provided in the *Aquatic Manual*.

Article 2.1.17.2.

Scope

The recommendations in this Chapter apply to: common carp (*Cyprinus carpio carpio*), ghost carp (*Cyprinus carpio goi)*, koi carp (*Cyprinus carpio koi*) and common carp hybrids (e.g. *Cyprinus carpio x Carassius auratus)*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Article 2.1.17.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any KHVD related conditions, regardless of the KHVD status of the *exporting country*, *zone* or *compartment*:

   a) For the species referred to in Article 2.1.17.2. being used for any purpose:

      i) *commodities* treated in a manner that kills the host and inactivates the *disease agent* e.g. leather made from fish skin, pasteurised products and ready to eat meals; and fish oil and fish meal intended for use in animal feeds ~~commercially sterile canned fish~~;

      ii) ~~leather made from fish skin~~ biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent*.

   b) The following *commodities* destined for human consumption from the species referred to in Article 2.1.17.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

      ~~i) chemically preserved products (e.g. smoked, salted, pickled, marinated, etc.);~~

      ~~ii) products (e.g. ready prepared meals and fish oil) that have been heat treated in a manner to ensure the inactivation of the pathogen;~~

      i~~i~~i) *eviscerated fish* (chilled or frozen) ~~packaged for direct retail trade~~;

      ii~~i~~v) fillets or cutlets (chilled or frozen);

      iii~~v~~) dried *eviscerated fish* (including air dried, flame dried and sun dried).

For the *commodities* referred to in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.1.17.2., other than those referred to in point 1 of Article 2.1.17.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.1.17.7. to 2.1.17.12. relevant to the KHVD status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of KHVD of any live *commodity* of a species not covered in Article 2.1.17.2. but which could reasonably be expected to be a potential KHV vector, the *Competent Authorities* should conduct a~~n~~ *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of KHVD, and the potential consequences, associated with the importation of the *commodity* prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.1.17.4.

Koi herpesvirus disease free country

A country may make a *self-declaration of freedom* from KHVD if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from KHVD if all the areas covered by the shared water are declared KHVD free countries or *zones* (see Article 2.1.17.5.).

1. A country where none of the *susceptible species* referred to in Article 2.1.17.2. is present may make a *self-*declaration of freedom from KHVD when basic biosecurity conditions have been continuously met in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.1.17.2. are present but there has never been any observed occurrence of the *disease* for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter 2.1.17. of the *Aquatic Manual*, may make a *self-declaration of freedom* from KHVD when *basic biosecurity conditions* have been continuously met in the country for at least the past 10 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 25 years, or where the *infection* status prior to *targeted surveillance* was unknown~~; for example because of~~ (e.g. the absence of conditions conducive to its clinical expression~~;~~ as described in Chapter 2.1.17. of the *Aquatic Manual*), may make a *self-declaration of freedom* from KHVD when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.1.17. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of KHV.]

OR

4. A country that has previously made a *self-declaration of freedom* from KHVD but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from KHVD again ~~until~~ when the following conditions have been met:

a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.1.17. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of KHV; and

d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

In the meantime, part of the non-affected area may be declared a free *zone* provided that it such part meets the conditions in point 3 of Article 2.1.17.5.

Article 2.1.17.5.

Koi herpesvirus disease free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from KHVD may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a KHVD free *zone* or *compartment* if all the *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.1.17.2. is present may be declared free from KHVD when *basic biosecurity conditions* have been continuously met in the *zone* or compartment for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.1.17.2. are present but there has never been any observed occurrence of the *disease* for at least the past 25 years despite conditions that are *conducive* to its clinical expression, as described in Chapter 2.1.17. of the *Aquatic Manual*, may be declared free from KHVD when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 10 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 25 years, or where the *infection* status prior to *targeted surveillance* was unknown, ~~for example~~ (e.g. because of the absence of conditions conducive to its clinical expression, as described in Chapter 2.1.17. of the *Aquatic Manual*), may be declared free from KHVD when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and 2.1.17. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of KHV ~~koi herpesvirus detection~~.

OR

4. A *zone* previously declared free from KHVD but in which the *disease* is subsequently detected may ~~not~~ be declared free from KHVD again ~~until~~ when the following conditions have been met:

a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 1.1.4. and 2.1.17. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of KHV ~~koi herpesvirus detection~~; and

d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

Article 2.1.17.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from KHVD following the provisions of points 1 or 2 of Articles 2.1.17.4. or 2.1.17.5. (as relevant) may maintain its status as KHVD free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from KHVD following the provisions of point 3 of Articles 2.1.17.4. or 2.1.17.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as KHVD free provided that conditions that are conducive to clinical expression of KHVD, as described in Chapter 2.1.17. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of KHVD, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.1.17.7.

Importation of live aquatic animals from a country, zone or compartment declared free from koi herpesvirus disease

When importing live *aquatic animals* of species referred to in Article 2.1.17.2. from a country, *zone* or *compartment* declared free from KHVD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.1.17.4. or 2.1.17.5. (as applicable), the place of production of the *commodity* is a country, *zone* or *compartment* declared free from KHVD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.1.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.17.3.Appendix XIV (contd)

Article 2.1.17.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from koi herpesvirus disease

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.1.17.2. from a country, *zone* or *compartment* not declared free from KHVD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

a) ~~1.~~ the direct delivery ~~in~~to and lifelong holding of the consignment in biosecure ~~*quarantine*~~ facilities for;

~~2.~~ ~~the~~ continuous isolation ~~of the imported *aquatic animals* and their first generation progeny~~ from the local environment; and

b)~~3.~~ the treatment of all effluent and waste materials in a manner that ensures inactivation of koi herpesvirus.

2. If the intention of the introduction is the establishment of a new stock, international standards, such as the Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES Code may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock health/disease history;

   c) take and test samples for KHV, pests and general health/disease status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for KHV and perform general examinations for pests and general health/disease status;

   g) if KHV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as KHVD free or specific pathogen free (SPF) for KHV;

   h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment.*

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.17.3.

Article 2.1.17.9.

Importation of live aquatic animals for processing for human consumption from a country, zone or compartment not declared free from koi herpesvirus disease

When importing, for processing for human consumption, live *aquatic animals* of species referred to in Article 2.1.17.2. from a country, *zone* or *compartment* not declared free from KHVD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

Appendix XIV (contd)

1. the consignment be delivered directly to and held in *quarantine* facilities for slaughter and processing to one of the products referred to in point 1 of Article 2.1.17.3. or other products authorised by the *Competent Authority*; and
2. all effluent and waste materials from the processing be treated in a manner that ensures inactivation of koi herpesvirus.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.17.3.

Article 2.1.17.10.

Importation of live aquatic animals intended for use in animal feed, or for agricultural, industrial or pharmaceutical use, from a country, zone or compartment not declared free from koi herpesvirus disease

When importing, for use in animal feed, or for agricultural, industrial or pharmaceutical use, live *aquatic animals* of species referred to in Article 2.1.17.2. from a country, *zone* or *compartment* not declared free from KHVD, the *Competent Authority* of the *importing country* should require that:

1. the consignment be delivered directly to and held in *quarantine* facilities for slaughter and processing to products authorised by the *Competent Authority*; and

2. all effluent and waste materials from the processing be treated in a manner that ensures inactivation of koi herpesvirus.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.17.3.

Article 2.1.17.11.

Importation of aquatic animal products from a country, zone or compartment declared free from koi herpesvirus disease

When importing *aquatic animal products* of species referred to in Article 2.1.17.2. from a country, *zone* or *compartment* declared free from KHVD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.1.17.4. or 2.1.17.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from KHVD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.1.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.17.3.

Article 2.1.17.12.

Importation of aquatic animal products from a country, zone or compartment not declared free from koi herpesvirus disease

When importing *aquatic animal products* of species referred to in Article 2.1.17.2. from a country, *zone* or *compartment* not declared free from KHVD, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

In the case of dead *aquatic animals*, whether *eviscerated* or uneviscerated, such risk mitigation measures may include:

1. the direct delivery into and holding of the consignment in biosecure/*quarantine* facilities for processing to one of the products referred to in point 1 of Article 2.1.17.3. or other products authorised by the *Competent Authority*;

2. the treatment of all effluent and waste materials in a manner that ensures inactivation of koi herpesvirus.

This Article does not apply to *commodities* referred to in point 1 of Article 2.1.17.3.

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Appendix XV

CHAPTER 2.3.1.

TAURA SYNDROME

Community Position
The Community supports the proposed chapter.

However, the Community would like the OIE to take into account the following comments, when addressing future amendments to the Code

1) Article 2.3.1.3. (Commodities)
Point 1 b). To require packaging for direct retail sale for commodities such as chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.). seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade"
An alternative solution would be to include those commodities in point 1.a).

2) Article 2.3.1.8. (Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Taura Syndrome)*
The Community maintains its concern about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in this case the ICES guidelines) because of the lack of clarity of the validity of such external documents and any changes made to.

3) Article 2.3.1.10 and 2.3.1.11 (Importation of aquatic animal products).
It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.3.1.2, the Competent Authority of the importing country shall asses the risk and, if justified, apply risk mitigation measures. The importing country should be informed of the outcome of this assement and of the risk mitigation measures to be applied.

The article does not apply to commodities referred to in point 1 of Article 2.3.1.3.

Article 2.3.1.1.

For the purposes of the *Aquatic Code*, Taura syndrome (TS) means *infection* with Taura syndrome virus (TSV). *Taura syndrome virus* is classified as a species in the family *Dicistroviridae*. Common synonyms are listed in Chapter 4.1.1. of the *Aquatic Manual*.

Methods for conducting surveillance and diagnosis of TS are provided in the *Aquatic Manual*.

Article 2.3.1.2.

Scope

The recommendations in this Chapter apply to: Pacific white shrimp or whiteleg shrimp (*Penaeus vannamei*), blue shrimp (*P. stylirostris*), northern white shrimp (*P. setiferus*), southern white shrimp (*P. schmitti*), greasyback prawn (*Metapenaeus ensis*) and giant tiger prawn (*P. monodon*). These recommendations also apply to any other susceptible species referred to in the Aquatic Manual when traded internationally.

For the purposes of this Chapter, the terms shrimp and prawn are used interchangeably.

Article 2.3.1.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any TS related conditions, regardless of the TS status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 2.3.1.2. being used for any purpose:

      i) *commodities* treated in a manner that inactivates the *disease agent* e.g. boiled, canned or pasteurised products and ready to eat meals; and crustacean oil and crustacean meal intended for use in animal feeds ~~commercially sterile canned products~~;

      ~~ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);~~

      ii~~i~~) chemically extracted chitin;

      ~~iv) crustacean meals or by products made non infectious by heating or drying (e.g. flame dried or sun dried);~~

      iii~~v~~) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

      i~~v~~) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent* ~~TSV~~ (e.g. formalin or alcohol preserved samples).

   b) The following products destined for human consumption from species referred to in Article 2.3.1.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

      i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.)~~;~~.

      ~~ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen.~~

   For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.1.2., other than those listed in point 1 of Article 2.3.1.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.1.7. to 2.3.1.11. relevant to the TS status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of TS of a~~ny other~~ *commodity* of a species not covered in Article 2.3.1.2. but which could reasonably be expected to be a potential TSV ~~carrier~~ vector, the *Competent Authorities* ~~of the *importing country*~~ should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of TSV, and the potential consequences, associated~~

~~with the importation of the *commodity* prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.1.4.

Taura syndrome free country

A country may make a *self-declaration of freedom* from TS if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from TS if all the areas covered by the shared water are declared TS free countries or *zones* (see Article 2.3.1.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.1.2. is present may make a *self-declaration of freedom* from TS when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.3.1.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from TS when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~, for example~~ (e.g. because of the absence of conditions conducive to its clinical expression~~;~~ as described in Chapter X.X.X. of the *Aquatic Manual*), may make a *self-declaration of freedom* from TS when:

   a) *basic biosecurity* conditions have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of TSV.

OR

4. A country that has previously made a *self-declaration of freedom* from TS but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from TS again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of TSV; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that ~~they~~ such part meets the conditions in point 3 of Article 2.3.1.5.

Article 2.3.1.5.

Taura syndrome free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from TS may be

declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a TS free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.3.1.2. is present may be declared free from TS when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.3.1.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from TS when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~,~~ ~~for example~~ (e.g. because of the absence of conditions conducive to its clinical expression~~,~~ as described in Chapter X.X.X. of the *Aquatic Manual*), may be declared free from TS when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of TSV.

OR

4. A *zone* previously declared free from TS but in which the *disease* is subsequently detected may ~~not~~ be declared free from TS again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of TSV; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

Article 2.3.1.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from TS following the provisions of points 1 or 2 of Articles 2.3.1.4. or 2.3.1.5. (as relevant) may maintain its status as TS free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from TS following the provisions of point 3 of Articles 2.3.1.4. or 2.3.1.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as TS

free provided that conditions that are conducive to clinical expression of TS, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of TS, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.3.1.7.

Importation of live aquatic animals from a country, zone or compartment declared free from Taura syndrome

When importing live *aquatic animals* of species referred to in Article 2.3.1.2. from a country, *zone* or *compartment* declared free from TS, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.1.4. or 2.3.1.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from TS.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.1.3.

Article 2.3.1.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from Taura syndrome

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.1.2. from a country, *zone* or *compartment* not declared free from TS, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

   a) the direct delivery ~~in~~to and lifelong holding of the consignment in biosecure ~~*quarantine*~~ facilities for;

   ~~b)~~ ~~the~~ continuous isolation ~~of the imported live *aquatic animals* and their first generation progeny~~ from the local environment; and

   ~~c)~~b) the treatment of all effluent and waste materials ~~from the processing~~ in a manner that ensures inactivation of TSV.

2. If the intention of the introduction is the establishment of a new stock ~~genetic lines~~, international standards, such as the ~~Guidelines~~ Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES ~~Guidelines~~ Code may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock health/disease history;

   c) take and test samples for TSV, pests and general health/disease status;

   d) import and quarantine in a secure facility a founder (F-0) population;

e) produce F-1 generation from the F-0 stock in *quarantine*;

f) culture F-1 stock and at critical times in its development (life cycle) sample and test for TSV and perform general examinations for pests and general health/disease status;

g) if TSV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as TS free or specific pathogen free (SPF) for TSV;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.1.3.

Article 2.3.1.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from Taura syndrome

When importing, for human consumption, live *aquatic animals* of species referred to in Article 4.1.1.2. from a country, *zone* or *compartment* not declared free from TS, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

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1. the consignment be delivered directly to and held in isolation until consumption; and

2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of TSV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.1.3.

Article 2.3.1.10.

Importation of aquatic animal products from a country, zone or compartment declared free from Taura syndrome

When importing *aquatic animal products* of species referred to in Article 2.3.1.2. from a country, *zone* or *compartment* declared free from TS, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.1.4. or 2.3.1.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from TS.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.1.3.

Article 2.3.1.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from Taura syndrome

When importing *aquatic animal products* of species referred to in Article 2.3.1.2. from a country, *zone* or

compartment not declared free from TS, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.1.3.

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CHAPTER 2.3.2.

WHITE SPOT DISEASE

Community Position
The Community supports the proposed chapter.

However, the Community would like the OIE to take into account the following comments, when addressing future amendments to the Code
1) Article 2.3.2.3. (Commodities)
Point 1 b). To require packaging for direct retail sale for commodities such as chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.) seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade"
An alternative solution would be to include those commodities in point 1.a).

2) Article 2.3.2.8. (Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *White spot disease)*
The Community maintains its concern about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in this case the ICES guidelines) because of the lack of clarity of the validity of such external documents and any changes made to.

3) Article 2.3.2.10 and 2.3.2.11 (Importation of aquatic animal products).

It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.3.2.2, the Competent Authority of the importing country shall asses the risk and, if justified, apply risk mitigation measures. The importing country should be informed of the outcome of this assement and of the risk mitigation measures to be applied.
The article does not apply to commodities referred to in point 1 of Article 2.3.2.3.

Article 2.3.2.1.

For the purposes of the *Aquatic Code*, white spot disease (WSD) means *infection* with white spot syndrome virus (WSSV). *White spot syndrome virus 1* is classified as a species in the genus *Whispovirus* of the family *Nimaviridae*. Common synonyms are listed in Chapter 4.1.2. of the *Aquatic Manual*.

Methods for conducting surveillance and diagnosis of WSD are provided in the *Aquatic Manual*.

Article 2.3.2.2.

Scope

The recommendations in this Chapter apply to all decapod (order *Decapoda*) crustaceans from marine, brackish and freshwater sources. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

For the purposes of this Chapter, the terms shrimp and prawn are used interchangeably.

Article 2.3.2.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any WSD related conditions, regardless of the WSD status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 2.3.2.2. being used for any purpose:

      i) *commodities* treated in a manner that inactivates the *disease agent* e.g. boiled, canned or pasteurised products and ready to eat meals; and crustacean oil and crustacean meal intended for use in animal feeds ~~commercially sterile canned products;~~

      ~~ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);~~

      ii~~i~~) chemically extracted chitin;

      ~~iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);~~

      iii~~v~~) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

      iv~~i~~) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent* ~~WSSV~~ (e.g. formalin or alcohol preserved samples).

   b) The following products destined for human consumption from species referred to in Article 4.1.2.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

      i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.)~~;~~.

      ~~ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen~~.

   For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.2.2., other than those listed in point 1 of Article 2.3.2.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.2.7. to 2.3.2.11. relevant to the WSD status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of WSD of a~~ny~~ ~~other~~ *commodity* of a species not covered in Article 2.3.2.2. but which could reasonably be expected to be a potential WSSV ~~carrier~~ vector, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of WSSV, and the potential consequences, associated with the importation of the *commodity* prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.2.4.

White spot disease free country

A country may make a *self-declaration of freedom* from WSD if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from WSD if all the areas covered by the shared water are declared WSD free countries or *zones* (see

Article 4.1.2.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.2.2. is present may make a *self-declaration of freedom* from WSD when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.3.2.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from WSD when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~; for example~~ because of the absence of conditions conducive to its clinical expression~~;~~ as described in Chapter X.X.X. of the *Aquatic Manual*), may make a *self-declaration of freedom* from WSD when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of WSSV.

OR

4. A country that has previously made a *self-declaration of freedom* from WSD but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from WSD again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of WSSV; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that ~~they~~ such part meets the conditions in point 3 of Article 2.3.2.5.

Article 2.3.2.5.

White spot disease free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from WSD may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a WSD free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.3.2.2. is present may be declared free from WSD when *basic biosecurity conditions* have been continuously met in the *zone* or

compartment for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.3.2.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from WSD when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~, for example~~ because of the absence of conditions conducive to its clinical expression~~,~~ as described in Chapter X.X.X. of the *Aquatic Manual*), may be declared free from WSD when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of WSSV.

OR

4. A *zone* previously declared free from WSD but in which the *disease* is subsequently detected may ~~not~~ be declared free from WSD again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of WSSV; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

Article 2.3.2.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from WSD following the provisions of points 1 or 2 of Articles 2.3.2.4. or 2.3.2.5. (as relevant) may maintain its status as WSD free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from WSD following the provisions of point 3 of Articles 2.3.2.4. or 2.3.2.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as WSD free provided that conditions that are conducive to clinical expression of WSD, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of WSD, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.3.2.7.

Importation of live aquatic animals from a country, zone or compartment declared free from white spot disease

When importing live *aquatic animals* of species referred to in Article 2.3.2.2. from a country, *zone* or *compartment* declared free from WSD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.2.4. or 2.3.2.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from WSD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.2.3

Article 2.3.2.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from white spot disease

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.2.2. from a country, *zone* or *compartment* not declared free from WSD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

   a) the direct delivery ~~in~~to and lifelong holding of the consignment in biosecure ~~*quarantine*~~ facilities for;

   ~~b)~~ ~~the~~ continuous isolation ~~of the imported live *aquatic animals* and their first generation progeny~~ from the local environment; and

   ~~c)~~b) the treatment of all effluent and waste materials ~~from the processing~~ in a manner that ensures inactivation of WSSV.

2. If the intention of the introduction is the establishment of a new stock ~~genetic lines~~, international standards, such as the ~~Guidelines~~ Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES ~~Guidelines~~ Code may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock health/*disease* history;

   c) take and test samples for WSSV, pests and general health/*disease* status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for WSSV and perform general examinations for pests and general health/*disease* status;

   g) if WSSV is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as WSD free or specific pathogen free (SPF) for WSSV;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.2.3.

Article 2.3.2.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from white spot disease

When importing, for human consumption, live *aquatic animals* of species referred to in Article 2.3.2.2. from a country, *zone* or *compartment* not declared free from WSD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment be delivered directly to and held in isolation until consumption; and

2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of WSSV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.2.3.

Article 2.3.2.10.

Importation of aquatic animal products from a country, zone or compartment declared free from white spot disease

When importing *aquatic animal products* of species referred to in Article 2.3.2.2. from a country, *zone* or *compartment* declared free from WSD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.2.4. or 2.3.2.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from WSD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.2.3.

Article 2.3.2.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from white spot disease

When importing *aquatic animal products* of species referred to in Article 2.3.2.2. from a country, *zone* or *compartment* not declared free from WSD, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.2.3.

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CHAPTER 2.3.3.

YELLOWHEAD DISEASE

Community Position
The Community supports the proposed chapter.

However, the Community would like the OIE to take into account the following comments, when addressing future amendments to the Code.

1) Article 2.3.3.3. (Commodities)
Point 1 b). To require packaging for direct retail sale for commodities such as chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.). seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade"
An alternative solution would be to include those commodities in point 1.a).

2) Article 2.3.3.8. (Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Yellowhead disease)*
The Community maintains its concern about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in this case the ICES guidelines) because of the lack of clarity of the validity of such external documents and any changes made to.

3) Article 2.3.3.10 and 2.3.3.11 (Importation of aquatic animal products).

It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.3.3.2, the Competent Authority of the importing country shall asses the risk and, if justified, apply risk mitigation measures. The importing country should be informed of the outcome of this assement and of the risk mitigation measures to be applied.
The article does not apply to commodities referred to in point 1 of Article 2.3.3.3.

Article 2.3.3.1.

For the purposes of the *Aquatic Code*, yellowhead disease (YHD) means *infection* with yellow head virus (YHV). YHV and the related *Gill-associated virus* are classified as a species in the genus *Okavirus*, family *Roniviridae* and order *Nidovirales*. Common synonyms are listed in Chapter 4.1.3. of the *Aquatic Manual*.

Methods for conducting surveillance and diagnosis of yellowhead disease are provided in the *Aquatic Manual*.

Article 2.3.3.2.

Scope

The recommendations in this Chapter apply to: giant tiger prawn (*Penaeus monodon*), brown tiger prawn (*P. esculentus*) and Kuruma prawn (*P. japonicus*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

For the purposes of this Chapter, the terms shrimp and prawn are used interchangeably.

Article 2.3.3.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any YHD related conditions, regardless of the YHD status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 2.3.3.2. being used for any purpose:

      i) *commodities* treated in a manner that inactivates the *disease agent* e.g. boiled, canned or pasteurised products and ready to eat meals; and crustacean oil and crustacean meal intended for use in animal feeds ~~commercially sterile canned products~~;

      ~~ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);~~

      ii~~i~~) chemically extracted chitin;

      ~~iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);~~

      iii~~v~~) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

      vi) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent* ~~YHV~~ (e.g. formalin or alcohol preserved samples).

   b) The following products destined for human consumption from species referred to in Article 2.3.3.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

      i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.)~~;~~.

      ~~ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen.~~

   For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.3.2., other than those listed in point 1 of Article 2.3.3.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.3.7. to 2.3.3.11. relevant to the YHD status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of YHD of a~~ny~~ ~~other~~ *commodity* of a species not covered in Article 2.3.3.2. but which could reasonably be expected to be a potential YHV ~~carrier~~ vector, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of YHV, and the potential consequences, associated with the importation of the commmodity prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.3.4.

Yellowhead disease free country

A country may make a *self-declaration of freedom* from YHD if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from YHD if all the areas covered by the shared water are declared YHD free countries or *zones* (see Article 2.3.3.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.3.2. is present may make a *self-declaration of freedom* from YHD when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.3.3.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from YHD when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~, for example~~ (e.g. because of the absence of conditions conducive to its clinical expression~~,~~ as described in Chapter X.X.X. of the *Aquatic Manual*), may make a *self-declaration of freedom* from YHD when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) targeted surveillance, as described in Chapters 1.1.4. and X.X.X. of the Aquatic Manual, has been in place for at least the last 2 years without detection of YHV.

OR

4. A country that has previously made a *self-declaration of freedom* from YHD but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from YHD again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of YHV; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that ~~they~~ such part meets the conditions in point 3 of Article 2.3.3.5.

Article 2.3.3.5.

Yellowhead disease free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from YHD may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a YHD free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.3.3.2. is present may be declared free from YHD when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.3.3.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from YHD when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~,~~ ~~for example~~ (e.g. because of the absence of conditions conducive to its clinical expression~~,~~ as described in Chapter X.X.X. of the *Aquatic Manual*), may be declared free from YHD when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of YHV.

OR

4. A *zone* previously declared free from YHD but in which the *disease* is subsequently detected may ~~not~~ be declared free from YHD again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of YHV; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

Article 2.3.3.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from YHD following the provisions of points 1 or 2 of Articles 2.3.3.4. or 2.3.3.5. (as relevant) may maintain its status as YHD free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from YHD following the provisions of point 3 of Articles 2.3.3.4. or 2.3.3.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as YHD free provided that conditions that are conducive to clinical expression of YHD, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are

not conducive to clinical expression of YHD, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.3.3.7.

Importation of live aquatic animals from a country, zone or compartment declared free from yellowhead disease

When importing live *aquatic animals* of species referred to in Article 2.3.3.2. from a country, *zone* or *compartment* declared free from YHD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.3.4. or 2.3.3.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from YHD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.3.3.

Article 2.3.3.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from yellowhead disease

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.3.2. from a country, *zone* or *compartment* not declared free from YHD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as:~~

   a) the direct delivery ~~in~~to and lifelong holding of the consignment in biosecure ~~*quarantine*~~ facilities for;

   ~~b)~~ ~~the~~ continuous isolation ~~of the imported live *aquatic animals* and their first generation progeny~~ from the local environment; and

   ~~c)~~b) the treatment of all effluent and waste materials ~~from the processing~~ in a manner that ensures inactivation of YHV.

2. If the intention of the introduction is the establishment of a new stock ~~genetic lines~~, international standards, such as the ~~Guidelines~~ Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES ~~Guidelines~~ Code may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock health/*disease* history;

   c) take and test samples for YHV, pests and general health/*disease* status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for YHV and perform general examinations for pests and general health/*disease* status;

   g) if YHV is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as YHD free or specific pathogen free (SPF) for YHV;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.3.3.

Article 2.3.3.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from yellowhead disease

When importing, for human consumption, live *aquatic animals* of species referred to in Article 2.3.3.2. from a country, *zone* or *compartment* not declared free from YHD, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

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1. the consignment be delivered directly to and held in isolation until consumption; and

2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of YHV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.3.3.

Article 2.3.3.10.

Importation of aquatic animal products from a country, zone or compartment declared free from yellowhead disease

When importing *aquatic animal products* of species referred to in Article 2.3.3.2. from a country, *zone* or *compartment* declared free from YHD, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.3.4. or 2.3.3.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from YHD.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.3.3.

Article 2.3.3.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from yellowhead disease

When importing *aquatic animal products* of species referred to in Article 2.3.3.2. from a country, *zone* or *compartment* not declared free from YHD, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.3.3.

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CHAPTER 2.3.4.

TETRAHEDRAL BACULOVIROSIS

Community Position
The Community supports the proposed chapter.

However, the Community would like the OIE to take into account the following comments, when addressing future amendments to the Code
1) Article 2.3.4.3. (Commodities)
Point 1 b). To require packaging for direct retail sale for commodities such as chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.). seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade"
An alternative solution would be to include those commodities in point 1.a).

2) Article 2.3.4.8.(Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Tetrahedral baculovirosis)*
The Community maintains its concern about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in this case the ICES guidelines) because of the lack of clarity of the validity of such external documents and any changes made to.

3) Article 2.3.4.10 and 2.3.4.11 (Importation of aquatic animal products).

It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.3.4.2, the Competent Authority of the importing country shall asses the risk and, if justified, apply risk mitigation measures. The importing country should be informed of the outcome of this assement and of the risk mitigation measures to be applied.
The article does not apply to commodities referred to in point 1 of Article 2.3.4.3.

Article 2.3.4.1.

For the purposes of the *Aquatic Code*, tetrahedral baculovirosis means *infection* with *Baculovirus penaei* (BPV). This virus is closely related to *Penaeus monodon baculovirus* (Chapter 4.1.5.) which has been classified as a tentative species in the genus *Nucleopolyhedrovirus*. Common synonyms are listed in Chapter 4.1.4. of the *Aquatic Manual*.

Methods for conducting surveillance and diagnosis of tetrahedral baculovirosis are provided in the *Aquatic Manual*.

Article 2.3.4.2.

Scope

The recommendations in this Chapter apply to the following genera: *Penaeus, Trachypenaeus* and *Protrachypene*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

For the purposes of this Chapter, the terms shrimp and prawn are used interchangeably.

Article 2.3.4.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any tetrahedral baculovirosis related conditions, regardless of the tetrahedral baculovirosis status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 2.3.4.2. being used for any purpose:

      i) *commodities* treated in a manner that inactivates the *disease agent* e.g. boiled, canned or pasteurised products and ready to eat meals; and crustacean oil and crustacean meal intended for use in animal feeds ~~commercially sterile canned products~~;

      ~~ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);~~

      ii~~i~~) chemically extracted chitin;

      ~~iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);~~

      iii~~v~~) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

      iv~~i~~) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent* ~~BPV~~ (e.g. formalin or alcohol preserved samples).

   b) The following products destined for human consumption from species referred to in Article 2.3.4.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

      i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.);

      ~~ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen;~~

      ii~~i~~) de-headed and ~~de-veined~~ "de-veined" (intestine removed) shrimp tails.

   For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.4.2., other than those listed in point 1 of Article 2.3.4.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.4.7. to 2.3.4.11., relevant to the tetrahedral baculovirosis status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of tetrahedral baculovirosis of a~~ny~~ ~~other~~ *commodity* of a species not covered in Article 2.3.4.2. but which could reasonably be expected to be a potential BPV ~~carrier~~ vector, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of BPV, and the potential consequences, associated with the importation of the *commodity* prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.4.4.

Tetrahedral baculovirosis free country

A country may make a *self-declaration of freedom* from tetrahedral baculovirosis if it meets the conditions in

points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from tetrahedral baculovirosis if all the areas covered by the shared water are declared tetrahedral baculovirosis free countries or *zones* (see Article 2.3.4.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.4.2. is present may make a *self-declaration of freedom* from tetrahedral baculovirosis when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.3.4.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from tetrahedral baculovirosis when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~,~~ ~~for example~~ (e.g. because of the absence of conditions conducive to its clinical expression~~,~~ as described in Chapter X.X.X. of the *Aquatic Manual*), may make a *self-declaration of freedom* from tetrahedral baculovirosis when:

   a) *basic biosecurity conditions have been continuously met for at least the past 2 years; and Appendix XVIII (contd)*

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of BPV.

OR

4. A country that has previously made a *self-declaration of freedom* from tetrahedral baculovirosis but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from tetrahedral baculovirosis again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of BPV; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that ~~they~~ such part meets the conditions in point 3 of Article 2.3.4.5.

Article 2.3.4.5.

Tetrahedral baculovirosis free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from tetrahedral baculovirosis may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a tetrahedral baculovirosis free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.3.4.2. is present may be declared free from tetrahedral baculovirosis when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.3.4.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from tetrahedral baculovirosis when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~,~~ ~~for example~~ (e.g. because of the absence of conditions conducive to its clinical expression~~,~~ as described in Chapter X.X.X. of the *Aquatic Manual*), may be declared free from tetrahedral baculovirosis when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of BPV.

OR

4. A *zone* previously declared free from tetrahedral baculovirosis but in which the *disease* is subsequently detected may ~~not~~ be declared free from tetrahedral baculovirosis again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of BPV; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

Article 2.3.4.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from tetrahedral baculovirosis following the provisions of points 1 or 2 of Articles 2.3.4.4. or 2.3.4.5. (as relevant) may maintain its status as tetrahedral baculovirosis free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from tetrahedral baculovirosis following the provisions of point 3 of Articles 2.3.4.4. or 2.3.4.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as tetrahedral baculovirosis free provided that conditions that are conducive to clinical expression

of tetrahedral baculovirosis, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of tetrahedral baculovirosis, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.3.4.7.

Importation of live aquatic animals from a country, zone or compartment declared free from tetrahedral baculovirosis

When importing live *aquatic animals* of species referred to in Article 2.3.4.2. from a country, *zone* or *compartment* declared free from tetrahedral baculovirosis, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.4.4. or 2.3.4.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from tetrahedral baculovirosis.

The certificate should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.4.3.

Article 2.3.4.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from tetrahedral baculovirosis

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.4.2. from a country, *zone* or *compartment* not declared free from tetrahedral baculovirosis, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

    a) the direct delivery ~~in~~to and lifelong holding of the consignment in biosecure ~~*quarantine*~~ facilities for;

    ~~b)~~ ~~the~~ continuous isolation ~~of the imported live *aquatic animals* and their first generation progeny~~ from the local environment; and

    ~~c)~~b) the treatment of all effluent and waste materials ~~from the processing~~ in a manner that ensures inactivation of BPV.

2. If the intention of the introduction is the establishment of a new stock ~~genetic lines~~, international standards, such as the ~~Guidelines~~ Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES ~~Guidelines~~ Code may be summarised to the following main points:

    a) identify stock of interest (cultured or wild) in its current location;

    b) evaluate stock health/*disease* history;

    c) take and test samples for BPV, pests and general health/*disease* status;

    d) import and quarantine in a secure facility a founder (F-0) population;

e) produce F-1 generation from the F-0 stock in *quarantine*;

f) culture F-1 stock and at critical times in its development (life cycle) sample and test for BPV and perform general examinations for pests and general health/*disease* status;

g) if BPV is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as tetrahedral baculovirosis free or specific pathogen free (SPF) for BPV;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.4.3.

Appendix XVIII (contd)

Article 2.3.4.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from tetrahedral baculovirosis

When importing, for human consumption, live *aquatic animals* of species referred to in Article 2.3.4.2. from a country, *zone* or *compartment* not declared free from tetrahedral baculovirosis, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment be delivered directly to and held in isolation until consumption; and

2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of BPV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.4.3.

Article 2.3.4.10.

Importation of aquatic animal products from a country, zone or compartment declared free from tetrahedral baculovirosis

When importing *aquatic animal products* of species referred to in Article 2.3.4.2. from a country, *zone* or *compartment* declared free from tetrahedral baculovirosis, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.4.4. or 2.3.4.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from tetrahedral baculovirosis.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.4.3.

Article 2.3.4.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from tetrahedral baculovirosis

When importing *aquatic animal products* of species referred to in Article 2.3.4.2. from a country, *zone* or *compartment* not declared free from tetrahedral baculovirosis, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.4.3.

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CHAPTER 2.3.5.

SPHERICAL BACULOVIROSIS

Community Position
The Community supports the proposed chapter.

However, the Community would like the OIE to take into account the following comments, when addressing future amendments to the Code.
1) Article 2.3.5.3. (Commodities)
Point 1 b). To require packaging for direct retail sale for commodities such as chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.). seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade"
An alternative solution would be to include those commodities in point 1.a).

2) Article 2.3.5.8. (Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Spherica baculovirosisl)*
The Community maintains its concern about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in this case the ICES guidelines) because of the lack of clarity of the validity of such external documents and any changes made to.

3) Article 2.3.5.10 and 2.3.5.11 (Importation of aquatic animal products).

It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.3.5.2, the Competent Authority of the importing country shall asses the risk and, if justified, apply risk mitigation measures. The importing country should be informed of the outcome of this assement and of the risk mitigation measures to be applied.
The article does not apply to commodities referred to in point 1 of Article 2.3.5.3.

Article 2.3.5.1.

For the purposes of the *Aquatic Code*, spherical baculovirosis means *infection* with *Penaeus monodon* baculovirus (MBV). *Penaeus monodon baculovirus* is classified as a tentative species in the genus *Nucleopolyhedrovirus*. Common synonyms are listed in Chapter 4.1.5. of the *Aquatic Manual*.

Methods for conducting surveillance and diagnosis of spherical baculovirosis are provided in the *Aquatic Manual*.

Article 2.3.5.2.

Scope

The recommendations in this Chapter apply to the following genera: *Penaeus* and *Metapenaeus*. These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

For the purposes of this Chapter, the terms shrimp and prawn are used interchangeably.

Article 2.3.5.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any spherical baculovirosis related conditions, regardless of the spherical baculovirosis status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 2.3.5.2. being used for any purpose:

      i) *commodities* treated in a manner that inactivates the *disease agent* e.g. boiled, canned or pasteurised products and ready to eat meals; and crustacean oil and crustacean meal intended for use in animal feeds ~~commercially sterile canned products~~;

      ~~ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);~~

      i~~i~~ii) chemically extracted chitin;

      ~~iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);~~

      iii~~v~~) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

      iv~~i~~) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent* ~~MBV~~ (e.g. formalin or alcohol preserved samples).

Appendix XIX (contd)

   b) The following products destined for human consumption from species referred to in Article 2.3.5.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

      i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.);

      ~~ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen;~~

      ~~i~~ii) de-headed and ~~de-veined~~ "de-veined" (intestine removed) shrimp tails.

   For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.5.2., other than those listed in point 1 of Article 2.3.5.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.5.7. to 2.3.5.11. relevant to the spherical baculovirosis status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of spherical baculovirosis of a~~ny~~ ~~other~~ *commodity* of a species not covered in Article 2.3.5.2. but which could reasonably be expected to be a potential MBV ~~carrier~~ vector, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of MBV, and the potential consequences, associated with the importation of the *commodity*, prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.5.4.

Spherical baculovirosis free country

A country may make a *self-declaration of freedom* from spherical baculovirosis if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from spherical baculovirosis if all the areas covered by the shared water are declared spherical baculovirosis free countries or *zones* (see Article 2.3.5.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.5.2. is present may make a *self-declaration of freedom* from spherical baculovirosis when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.3.5.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from spherical baculovirosis when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~, for example~~ (e.g. because of the absence of conditions conducive to its clinical expression~~,~~ as described in Chapter X.X.X. of the *Aquatic Manual*), may make a *self-declaration of freedom* from spherical baculovirosis when:

   a) basic biosecurity conditions have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 2 years without detection of MBV.

OR

4. A country that has previously made a *self-declaration of freedom* from spherical baculovirosis but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from spherical baculovirosis again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of MBV; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that they meet the conditions in point 3 of Article 2.3.5.5.

Article 2.3.5.5.

Spherical baculovirosis free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from spherical baculovirosis may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone*

or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a spherical baculovirosis free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.3.5.2. is present may be declared free from spherical baculovirosis when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.3.5.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from spherical baculovirosis when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~,~~ ~~for example~~ (e.g. because of the absence of conditions conducive to its clinical expression~~,~~ as described in Chapter X.X.X. of the *Aquatic Manual*), may be declared free from spherical baculovirosis when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of MBV.

OR

4. A *zone* previously declared free from spherical baculovirosis but in which the *disease* is detected may ~~not~~ be declared free from spherical baculovirosis again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of MBV; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

Article 2.3.5.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from spherical baculovirosis following the provisions of points 1 or 2 of Articles 2.3.5.4. or 2.3.5.5. (as relevant) may maintain its status as spherical baculovirosis free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from spherical baculovirosis following the provisions of point 3 of Articles 2.3.5.4. or 2.3.5.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as spherical baculovirosis free provided that conditions that are conducive to clinical expression of

spherical baculovirosis, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of spherical baculovirosis, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.3.5.7.

Importation of live aquatic animals from a country, zone or compartment declared free from spherical baculovirosis

When importing live *aquatic animals* of species referred to in Article 2.3.5.2. from a country, *zone* or *compartment* declared free from spherical baculovirosis, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.5.4. or 2.3.5.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from spherical baculovirosis.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.5.3.

Article 2.3.5.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from spherical baculovirosis

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.5.2. from a country, *zone* or *compartment* not declared free from spherical baculovirosis, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

   a) the direct delivery ~~in~~to and lifelong holding of the consignment in biosecure ~~*quarantine*~~ facilities for;

   ~~b)~~ ~~the~~ continuous isolation ~~of the imported live *aquatic animals* and their first generation progeny~~ from the local environment; and

   ~~c)~~b) the treatment of all effluent and waste materials ~~from the processing~~ in a manner that ensures inactivation of MBV.

2. If the intention of the introduction is the establishment of a new stock ~~genetic lines~~, international standards, such as the ~~Guidelines~~ Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES ~~Guidelines~~ Code may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock health/*disease* history;

   c) take and test samples for MBV, pests and general health/*disease* status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for MBV and perform general examinations for pests and general health/*disease* status;

g) if MBV is not detected, pests are not present, and the general health/disease status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as spherical baculovirosis free or specific pathogen free (SPF) for MBV;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.5.3.

Article 2.3.5.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from spherical baculovirosis

When importing, for human consumption, live *aquatic animals* of species referred to in Article 2.3.5.2. from a country, *zone* or *compartment* not declared free from spherical baculovirosis, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment be delivered directly to and held in isolation until consumption; and

2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of MBV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.5.3.

Article 2.3.5.10.

Importation of aquatic animal products from a country, zone or compartment declared free from spherical baculovirosis

When importing *aquatic animal products* of species referred to in Article 2.3.5.2. from a country, *zone* or *compartment* declared free from spherical baculovirosis, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.5.4. or 2.3.5.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from spherical baculovirosis.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.5.3.

Article 2.3.5.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from spherical baculovirosis

When importing *aquatic animal products* of species referred to in Article 2.3.5.2. from a country, *zone* or *compartment* not declared free from spherical baculovirosis, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.5.3.

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CHAPTER 2.3.6.

INFECTIOUS HYPODERMAL AND HAEMATOPOIETIC NECROSIS

Community Position
The Community supports the proposed chapter.

However, the Community would like the OIE to take into account the following comments, when addressing future amendments to the Code
1) Article 2.3.6.3. (Commodities)
Point 1 b). To require packaging for direct retail sale for commodities such as chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.). seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade"
An alternative solution would be to include those commodities in point 1.a).

2) Article 2.3.6.8. (Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from *Infectious hypodermal and haemotopoietic necrosis)*
The Community maintains its concern about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in this case the ICES guidelines) because of the lack of clarity of the validity of such external documents and any changes made to.

3) Article 2.3.6.10 and 2.3.6.11 (Importation of aquatic animal products).

It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.3.6.2, the Competent Authority of the importing country shall asses the risk and, if justified, apply risk mitigation measures. The importing country should be informed of the outcome of this assement and of the risk mitigation measures to be applied.
The article does not apply to commodities referred to in point 1 of Article 2.3.6.3.

Article 2.3.6.1.

For the purposes of the *Aquatic Code*, infectious hypodermal and haematopoietic necrosis (IHHN) means *infection* with infectious hypodermal and haematopoietic necrosis virus (IHHNV). IHHNV is classified as the species *Penaeus stylirostris densovirus* in the genus *Brevidensovirus* in the family *Parvoviridae*.

Methods for conducting surveillance and diagnosis of IHHN are provided in the *Aquatic Manual*.

Article 2.3.6.2.

Scope

The recommendations in this Chapter apply to: giant tiger prawn (*Penaeus monodon*), Pacific white shrimp (*P. vannamei*) and blue shrimp (*P. stylirostris*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

For the purposes of this Chapter, the terms shrimp and prawn are used interchangeably.

Article 2.3.6.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any IHHN related conditions, regardless of the IHHN status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 2.3.6.2. being used for any purpose:

      i) *commodities* treated in a manner that inactivates the *disease agent* e.g. boiled, canned or pasteurised products and ready to eat meals; and crustacean oil and crustacean meal intended for use in animal feeds ~~commercially sterile canned products~~;

      ~~ii) boiled products (e.g. boiled whole shrimp or tails, lobsters, crabs);~~

      ii~~i~~) chemically extracted chitin;

      ~~iv) crustacean meals or by-products made non-infectious by heating or drying (e.g. flame dried or sun dried);~~

      iii~~v~~) crustacean products made non-infectious through processing as dry feeds (e.g. pelleted or extruded feeds);

      iv~~i~~) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent* ~~IHHNV~~ (e.g. formalin or alcohol preserved samples).

   b) The following products destined for human consumption from species referred to in Article 4.1.6.2 which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

Appendix XX (contd)

      i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.)~~;~~,

      ~~ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen.~~

   For the *commodities* listed in point 1b), Member Countries should consider introducing internal measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.6.2., other than those listed in point 1 of Article 2.3.6.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.6.7. to 2.3.6.11. relevant to the IHHN status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of IHHN of a~~ny~~ ~~other~~ *commodity* of a species not covered in Article 2.3.6.2. but which could reasonably be expected to be a potential IHHNV ~~carrier~~ vector, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code* ~~of the risk of introduction, establishment and spread of IHHNV, and the potential consequences, associated with the importation of the *commodity* prior to a decision~~. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.6.4.

Infectious hypodermal and haematopoietic necrosis free country

A country may make a *self-declaration of freedom* from IHHN if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *zone* with one or more other countries, it can only make a *self-declaration of freedom* from IHHN if all the areas covered by the shared water are declared IHHN free countries or *zones* (see Article 2.3.6.5.).

1. A country where none of the *susceptible species* referred to in Article 2.3.6.2. is present may make a *self-declaration of freedom* from IHHN when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 2.3.6.2. are present but there has never been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from IHHN when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~, for example~~ (e.g. because of the absence of conditions conducive to its clinical expression~~,~~ as described in Chapter X.X.X. of the *Aquatic Manual*), may make a *self-declaration of freedom* from IHHN when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

b) targeted surveillance, as described in Chapters 1.1.4. and X.X.X. of the Aquatic Manual, has been in place for at least the last 2 years without detection of IHHNV.

OR

4. A country that has previously made a *self-declaration of freedom* from IHHN but in which the *disease* is subsequently detected may ~~not~~ make a *self-declaration of freedom* from IHHN again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of IHHNV; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

   In the meantime, part of the non-affected area may be declared a free *zone* provided that ~~they~~ such part meets the conditions in point 3 of Article 2.3.6.5.

Article 2.3.6.5.

Infectious hypodermal and haematopoietic necrosis free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from IHHN may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets

the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared an IHHN free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none of the *susceptible species* referred to in Article 2.3.6.2. is present may be declared free from IHHN when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 2.3.6.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from IHHN when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years, or where the *infection* status prior to *targeted surveillance* was unknown~~,~~ ~~for example~~ (e.g. because of the absence of conditions conducive to its clinical expression~~,~~ as described in Chapter X.X.X. of the *Aquatic Manual*~~)~~, may be declared free from IHHN when:

   a) *basic biosecurity conditions* have been continuously met for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of IHHNV.

OR

4. A *zone* previously declared free from IHHN but in which the *disease* is subsequently detected may ~~not~~ be declared free from IHHN again ~~until~~ when the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

   b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

   c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of IHHNV; and

   d) previously existing *basic biosecurity conditions* have been reviewed and modified as necessary and have continuously been in place for at least the past 2 years.

Article 2.3.6.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from IHHN following the provisions of points 1 or 2 of Articles 2.3.6.4. or 2.3.6.5. (as relevant) may maintain its status as IHHN free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from IHHN following the provisions of point 3 of Articles 2.3.6.4. or 2.3.6.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as IHHN

free provided that conditions that are conducive to clinical expression of IHHN, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of IHHN, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.3.6.7.

Importation of live aquatic animals from a country, zone or compartment declared free from infectious hypodermal and haematopoietic necrosis

When importing live *aquatic animals* of species referred to in Article 2.3.6.2. from a country, *zone* or *compartment* declared free from IHHN, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.6.4. or 2.3.6.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from IHHN.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to commodities listed in point 1 of Article 2.3.6.3.

Article 2.3.6.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from infectious hypodermal and haematopoietic necrosis

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.6.2. from a country, *zone* or *compartment* not declared free from IHHN, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

   a) the direct delivery ~~in~~to and lifelong holding of the consignment in biosecure ~~*quarantine*~~ facilities for;

   ~~b)~~ ~~the~~ continuous isolation ~~of the imported live *aquatic animals* and their first generation progeny~~ from the local environment; and

   ~~c)~~b) the treatment of all effluent and waste materials ~~from the processing~~ in a manner that ensures inactivation of IHHNV.

2. If the intention of the introduction is the establishment of a new stock ~~genetic lines~~, international standards, such as the ~~Guidelines~~ Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES ~~Guidelines~~ Code may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock health/*disease* history;

   c) take and test samples for IHHNV, pests and general health/*disease* status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

f) culture F-1 stock and at critical times in its development (life cycle) sample and test for IHHNV and perform general examinations for pests and general health/*disease* status;

g) if IHHNV is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as IHHN free or specific pathogen free (SPF) for IHHNV;

h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.6.3.

Article 2.3.6.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from infectious hypodermal and haematopoietic necrosis

When importing, for human consumption, live *aquatic animals* of species referred to in Article 2.3.6.2. from a country, *zone* or *compartment* not declared free from IHHN, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment be delivered directly to and held in isolation until consumption; and

2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of IHHNV.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.6.3.

Article 2.3.6.10.

Importation of aquatic animal products from a country, zone or compartment declared free from infectious hypodermal and haematopoietic necrosis

When importing *aquatic animal products* of species referred to in Article 2.3.6.2. from a country, *zone* or *compartment* declared free from IHHN, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.6.4. or 2.3.6.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from IHHN.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.6.3.

Article 2.3.6.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from infectious hypodermal and haematopoietic necrosis

When importing *aquatic animal products* of species referred to in Article 2.3.6.2. from a country, *zone* or *compartment* not declared free from IHHN, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.6.3.

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CHAPTER 2.3.7.

CRAYFISH PLAGUE

Community Position

1) Articles 2.3.7.4. and 2.3.7.5. Crayfish plague free country, zone and compartment

The Comunity cannot support the proposed chapters. Now the only alternative given for a disease free country, zone and compartment is that there are no susceptible species present. If only this alternative is chosen then there is no reason to have crayfish plague on the list. Although there are weaknesses in diagnostic methods concerning surveillance the Community wish to remind that there still are crayfish plague free countries, e.g. Australia and several islands, where crayfish plague is likely to cause acute and noticeable disease outbreak if this disease agent is imported. The Community position is that at least point 2 should be restored, or to retain articles 2.3.7.4. (free country) and 2.3.7.5. (free zone and compartment) as they were in the October 2006 report (article 4.1.7.4. and 4.1.7.5., respectively, in October report).
There is ongoing research aiming to develop and validate reliable diagnostic methods for the detection of crayfish plague carriers. Thus, the possibility to claim e.g. separate compartments disease free should become available in the future. The Community suggests that an expert group would address future amendments to the Code.

In addition, the Community would like the OIE to take into account the following comments, when addressing future amendments to the Code

A) Article 2.3.7.3. (Commodities)
Point 1 b). To require packaging for direct retail sale for commodities such as chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.). seems unjustified as these commodities pose a low risk to animal health. We would propose to delete the reference to "packaged for direct retail trade"
An alternative solution would be to include those commodities in point 1.a).

B) Article 2.3.7.8. (Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from*Crayfish plague*)
The Community maintains its concern about the use of reference in the Aquatic Code to documents outside the Aquatic Code (in this case the ICES guidelines) because of the lack of clarity of the validity of such external documents and any changes made to.

C) Article 2.3.7.10 and 2.3.7.11 (Importation of aquatic animal products).

It seems unjustified to require either freedom from the disease in the country of origin or implementation of risk mitigation measures on destination when importing aquatic animal products, taking into account the definition of aquatic animal products (non-viable aquatic animals and products from aquatic animals) which by nature cannot be for further farming. The Community would suggest that the OIE merges both articles. The new article would read:

Importation of aquatic animal products
When importing *aquatic animal products* of species referred to in article 2.3.7.2, the Competent Authority of the importing country shall asses the risk and, if justified, apply risk mitigation measures. The importing country should be informed of the outcome of this assement and of the risk mitigation measures to be applied.
The article does not apply to commodities referred to in point 1 of Article 2.3.7.3.

Article 2.3.7.1.

For the purposes of the *Aquatic Code*, crayfish plague means *infection* with *Aphanomyces astaci* Schikora. This

organism is a member of a group commonly known as the water moulds (the Oomycetida). Common synonyms are listed in Chapter 4.1.7. of the *Aquatic Manual*.

Methods for conducting surveillance and diagnosis of crayfish plague are provided in the *Aquatic Manual*.

Article 2.3.7.2.

Scope

The recommendations in this Chapter apply to all species of crayfish in all three crayfish families (*Cambaridae*, *Astacidae*, and *Parastacidae*). These recommendations also apply to any other *susceptible species* referred to in the *Aquatic Manual* when traded internationally.

Crayfish plague is most severe in European crayfish species including the noble crayfish (*Astacus astacus*), the white claw crayfish (*Austropotamobius pallipes*), stone crayfish (*Austropotamobius torrentium*), and the Turkish crayfish (*Astacus leptodactylus*). In general, the Parastacidae and the Astacidae (except N. American genera such as *Pacifastacus*) are highly susceptible, while the Cambaridae are resistant to *disease*, but are potential carriers.

There is some evidence of transfer by movement of fish (and their transport water) from waters containing infected crayfish.

Article 2.3.7.3.

Commodities

1. When authorising the importation or transit of the following *commodities*, the *Competent Authorities* should not require any crayfish plague related conditions, regardless of the crayfish plague status of the *exporting country*, *zone* or *compartment*.

   a) For the species referred to in Article 2.3.7.2. being used for any purpose:

      i) *commodities* treated in a manner that inactivates the *disease agent* e.g. cooked (for >2 minutes at 60°), canned or pasteurised products and ready to eat meals; and crustacean oil and crustacean meal intended for use in animal feeds ~~commercially sterile canned products~~;

      ~~ii) boiled products (e.g. cooked whole shrimp or tails, lobsters, crabs);~~

      ii~~i~~) chemically extracted chitin;

      ~~iv) crustacean meals or by-products made non-infectious by heating (>60°C for >5 minutes) or drying by-product (e.g. flame dried or sun dried);~~

      iii~~v~~) crustacean products made non-infectious during processing as dry feeds (e.g. pelleted or extruded feeds);

      i~~v~~) biological samples preserved for diagnostic applications in such a manner as to inactivate the *disease agent* ~~*A. astaci*~~ (e.g. formalin or alcohol preserved samples);

      v~~ii~~) frozen products that have been subjected to -~~10~~20°C or lower temperatures for at least ~~24~~ 72 hours.

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   b) The following products destined for human consumption from species referred to in Article 2.3.7.2. which have been prepared and packaged for direct retail trade ~~in such a way as to minimise the likelihood of alternative uses~~:

      i) chemically preserved products (e.g. salted, pickled, marinated, pastes, etc.)~~;~~.

      ~~ii) products that have been heat treated or dried (e.g. ready prepared meals) in a manner to ensure the inactivation of the pathogen.~~

   For the *commodities* listed in point 1b), Member Countries should consider introducing internal

measures to prevent the *commodity* being used for any purpose other than for human consumption.

2. When authorising the importation or transit of the *commodities* of a species referred to in Article 2.3.7.2., other than those listed in point 1 of Article 2.3.7.3., the *Competent Authorities* should require the conditions prescribed in Articles 2.3.7.7. to 2.3.7.11. relevant to the crayfish plague status of the *exporting country*, *zone* or *compartment*.

3. When considering the importation/transit from an *exporting country*, *zone* or *compartment* not declared free of crayfish plague of any other *commodity* of a species not covered in Article 2.3.7.2. but which could reasonably be expected to be a potential *A. astaci* carrier vector, the *Competent Authorities* should conduct a *risk analysis* in accordance with the recommendations in the *Aquatic Code* of the risk of introduction, establishment and spread of *A. astaci*, and the potential consequences, associated with the importation of the *commodity* prior to a decision. The *exporting country* should be informed of the outcome of this assessment.

Article 2.3.7.4.

Crayfish plague free country

A country may make a *self-declaration of freedom* from crayfish plague if it meets the conditions in points 1, 2, 3 or 4 below.

If a country shares a *water catchment* or with one or more other countries, it can only make a *self-declaration of freedom* from crayfish plague if all the areas covered by the shared water are declared crayfish plague free countries or *zones* (see Article 2.3.7.5.).

1. A country where none neither of the *susceptible species* or potential carrier species referred to in Article 2.3.7.2. is are present may make a *self-declaration of freedom* from crayfish plague when *basic biosecurity conditions* have been continuously met in the country for at least the past 2 years.

OR

2. A country where the *susceptible species* referred to in Article 4.1.7.2. are present but there has never been any observed occurrence of the *disease* for at least the past 25 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may make a *self-declaration of freedom* from crayfish plague when *basic biosecurity conditions* have been met continuously in the country for at least the past 2 years.

OR

3. A country where the last observed occurrence of the disease was within the past 25 years or where the infection status prior to targeted surveillance was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the Aquatic Manual, may make a self-declaration of freedom from crayfish plague when:

   a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

   b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the last 5 years without detection of *A. astaci*.

OR

4. A country that has previously made a *self-declaration of freedom* from crayfish plague but in which the *disease* is subsequently detected may not make a *self-declaration of freedom* from crayfish plague again until the following conditions have been met:

   a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and

c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 5 years without detection of *A. astaci*.

In the meantime, part of the non affected area may be declared a free *zone* provided that they meet the conditions in point 3 of Article 4.1.7.5.

Article 2.3.7.5.

Crayfish plague free zone or free compartment

A *zone* or *compartment* within the *territory* of one or more countries not declared free from crayfish plague may be declared free by the *Competent Authority(ies)* of the country(ies) concerned if the *zone* or *compartment* meets the conditions referred to in points 1, 2, 3 or 4 below.

If a *zone* or *compartment* extends over more than one country, it can only be declared a crayfish plague free *zone* or *compartment* if all the relevant *Competent Authorities* confirm that the conditions have been met.

1. A *zone* or *compartment* where none neither of the *susceptible species* or potential carrier species referred to in Article 2.3.7.2. is are present may be declared free from crayfish plague when *basic biosecurity conditions* have been continuously met in the *zone* or *compartment* for at least the past 2 years.

OR

2. A *zone* or *compartment* where the *susceptible species* referred to in Article 4.1.7.2. are present but in which there has not been any observed occurrence of the *disease* for at least the past 10 years despite conditions that are conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from crayfish plague when *basic biosecurity conditions* have been met continuously in the *zone* or *compartment* for at least the past 2 years.

OR

3. A *zone* or *compartment* where the last observed occurrence of the *disease* was within the past 10 years or where the *infection* status prior to *targeted surveillance* was unknown, for example because of the absence of conditions conducive to its clinical expression, as described in Chapter X.X.X. of the *Aquatic Manual*, may be declared free from crayfish plague when:

a) *basic biosecurity conditions* have been met continuously for at least the past 2 years; and

b) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place, through the *zone* or *compartment*, for at least the past 2 years without detection of *A. astaci*.

OR

4. A *zone* previously declared free from crayfish plague but in which the *disease* is detected may not be declared free from crayfish plague again until the following conditions have been met:

a) on detection of the *disease*, the affected area was declared an *infected zone* and a *buffer zone* was established; and

~~b) infected populations have been destroyed or removed from the *infected zone* by means that minimise the risk of further spread of the *disease*, and the appropriate *disinfection* procedures (see *Aquatic Manual*) have been completed; and~~

~~c) *targeted surveillance*, as described in Chapters 1.1.4. and X.X.X. of the *Aquatic Manual*, has been in place for at least the past 2 years without detection of *A. astaci*.~~

Article 2.3.7.6.

Maintenance of free status

A country, *zone* or *compartment* that is declared free from crayfish plague following the provisions of points 1 or 2 of Articles 2.3.7.4. or 2.3.7.5. (as relevant) may maintain its status as crayfish plague free provided that *basic biosecurity conditions* are continuously maintained.

A country, *zone* or *compartment* that is declared free from crayfish plague following the provisions of point 3 of Articles 2.3.7.4. or 2.3.7.5. (as relevant) may discontinue *targeted surveillance* and maintain its status as crayfish plague free provided that conditions that are conducive to clinical expression of crayfish plague, as described in Chapter X.X.X. of the *Aquatic Manual*, exist, and *basic biosecurity conditions* are continuously maintained.

However, for declared free *zones* or *compartments* in infected countries and in all cases where conditions are not conducive to clinical expression of crayfish plague, *targeted surveillance* needs to be continued at a level determined by the *Competent Authority* on the basis of the likelihood of *infection*.

Article 2.3.7.7.

Importation of live aquatic animals from a country, zone or compartment declared free from crayfish plague

When importing live *aquatic animals* of species referred to in Article 2.3.7.2. from a country, *zone* or *compartment* declared free from crayfish plague, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.7.4. or 2.3.7.5. (as applicable), the place of production of the *commodity* ~~consignment~~ is a country, *zone* or *compartment* declared free from crayfish plague.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.1.3.

This Article does not apply to commodities listed in point 1 of Article 2.3.7.3

Article 2.3.7.8.

Importation of live aquatic animals for aquaculture from a country, zone or compartment not declared free from crayfish plague

1. When importing, for *aquaculture*, live *aquatic animals* of species referred to in Article 2.3.7.2. from a country, *zone* or *compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, apply the following risk mitigation measures ~~such as~~:

   a) the direct delivery ~~in~~to and lifelong holding of the consignment in biosecure ~~*quarantine*~~ facilities for;

   ~~b)~~ ~~the~~ continuous isolation ~~of the imported live *aquatic animals* and their first generation progeny~~ from the local environment; and

   ~~c)~~b) the treatment of all effluent and waste materials ~~from the processing~~ in a manner that ensures inactivation of *A. astaci*.

2. If the intention of the introduction is the establishment of a new stock ~~genetic lines~~, international standards, such as the ~~Guidelines~~ Code of Practice on the Introductions and Transfers of Marine Organisms of the International Council for the Exploration of the Seas (ICES), should be followed.

3. For the purposes of the *Aquatic Code*, the ICES ~~Guidelines~~ Code may be summarised to the following main points:

   a) identify stock of interest (cultured or wild) in its current location;

   b) evaluate stock health/*disease* history;

   c) take and test samples for *A. astaci*, pests and general health/*disease* status;

   d) import and quarantine in a secure facility a founder (F-0) population;

   e) produce F-1 generation from the F-0 stock in *quarantine*;

   f) culture F-1 stock and at critical times in its development (life cycle) sample and test for *A. astaci* and perform general examinations for pests and general health/*disease* status;

   g) if *A. astaci* is not detected, pests are not present, and the general health/*disease* status of the stock is considered to meet the *basic biosecurity conditions* of the *importing country*, *zone* or *compartment*, the F-1 stock may be defined as crayfish plague free or specific pathogen free (SPF) for *A. astaci*;

   h) release SPF F-1 stock from *quarantine* for *aquaculture* or stocking purposes in the country, *zone* or *compartment*.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.7.3.

Article 2.3.7.9.

Importation of live aquatic animals for human consumption from a country, zone or compartment not declared free from crayfish plague

When importing, for human consumption, live *aquatic animals* of species referred to in Article 2.3.7.2. from a country, *zone* or *compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should assess the *risk* and, if justified, require that:

1. the consignment be delivered directly to and held in isolation until consumption; and

2. all effluent, dead *aquatic animals* and waste materials from the processing be treated in a manner that ensures inactivation of *A. astaci*.

Member Countries should consider introducing internal measures to prevent such *commodities* being used for any purpose other than for human consumption.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.7.3.

Article 2.3.7.9. bis.

Importation of live fish from a country, zone or compartment not declared free from crayfish plague

Because live fish and their transport water are potential vectors of crayfish plague, the *Competent Authority* of the *importing country* should require appropriate treatment of transport water as indicated in Chapter 1.5.1., when importing live fish from a country, *zone* or *compartment* not declared free from crayfish plague.

Article 2.3.7.10.

Importation of aquatic animal products from a country, zone or compartment declared free from crayfish plague

When importing *aquatic animal products* of species referred to in Article 2.3.7.2. from a country, *zone* or *compartment* declared free from crayfish plague, the *Competent Authority* of the *importing country* should require an *international aquatic animal health certificate* issued by the *Competent Authority* of the *exporting country* or a *certifying official* approved by the *importing country* attesting that, on the basis of the procedures described in Articles 2.3.7.4. or 2.3.7.5. (as applicable), the place of production of the consignment is a country, *zone* or *compartment* declared free from crayfish plague.

The *certificate* should be in accordance with the Model Certificate in Appendix 4.2.2.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.7.3.

Article 2.3.7.11.

Importation of aquatic animal products from a country, zone or compartment not declared free from crayfish plague

When importing *aquatic animal products* of species referred to in Article 2.3.7.2. from a country, *zone* or *compartment* not declared free from crayfish plague, the *Competent Authority* of the *importing country* should assess the risk and apply appropriate risk mitigation measures.

This Article does not apply to *commodities* listed in point 1 of Article 2.3.7.3.

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CHAPTER 2.1.17.

KOI HERPESVIRUS DISEASE

Community position

The Community supports the proposed chapter.

However, the Community would like the OIE to take into account the following comments, when addressing future amendments to the Code.

Under b) *Host factors* some fish species should be added, which are nonsusceptible to KHV, but have been cohabitated with KHV positive Cyprinus carpio:
Pike *(Esox lucius)*, gold orfe *(Leuciscus idus*, var. *auratus),* ornamental sturgeon species *(Acipenser species)* and bighead *(Aristichthys nobilis)* (Hoffmann, 2000, 2001; Schlotfeldt, 2004)
References

Hoffmann, R. (2000). Koiseuche bedroht Karpfenteichwirtschaft. Fischer und Teichwirt 11: 432.

Hoffmann, R., Just, F., and El-Matbouli, M., 2001. Koi Herpes Virus infection in Koi and common carp in Germany. Abstract of oral presentation at EAFP Conference, Dublin, Sept 2001.

(This one is already in the chapter)Schlotfeldt, H.-J., 2004. Severe losses of common carp in Germany due to Koi Herpesvirus (KHV). Letter to the editor, Bull. E.A.F.P. 24(5): 216-217.

1. Case definition

Koi herpesvirus disease (KHVD) is a herpesvirus infection (17) capable of inducing a contagious and acute viraemia in common carp (Cyprinus carpio) and varieties such as koi carp and ghost carp (15).

2. Information for the design of surveillance programmes

a) Agent factors

The aetiological agent is koi herpesvirus (KHV) in the family Herpesviridae (17, 40) although it has also been given the name carp interstitial nephritis and gill necrosis virus (CNGV) (19, 28). Waltzek *et al.* (39) provided evidence to support the classification of the virus as a herpesvirus, and named it cyprinid herpesvirus 3 (CyHV-3) following the nomenclature of other cyprinid herpesviruses: CyHV-1 (carp pox virus, fish papilloma) and CyHV-2 (goldfish haematopoietic necrosis virus). Estimates of the genome size of KHV vary from at least 150 kbp (11) to 277 kbp (19) to 295 kbp (39). Four genes coding for a helicase, an intercapsomeric triplex protein, DNA polymerase, and major capsid protein have been identified, and sequence analysis of these genes has shown that KHV is closely related to CyHV-1 and CyHV-2, and distantly related to channel catfish virus virus (Ictalurid herpesvirus: IcHV-1) (39). Estimates of virion size also vary. Nucleocapsids of negative stained virus have been measured at 103–112 nm diameter surrounded

by an envelope (17, 19, 37). The nucleocapsids of thin sectioned virus have been measured at 80–110 and 110–120 nm in diameter (4, 17, 26).

Serum from koi carp containing antibodies to KHV have been shown to cross-react with CyHV-1, a further indication that these viruses are closely related. Evidence of cross reacting antibodies was demonstrated in reciprocal enzyme-linked immunosorbent assay (ELISA) and western blot analyses of serum from koi infected with CyHV-1 or KHV (1).

Comparisons of the genomes of KHV isolates from different geographical areas by restriction enzyme analysis (9, 15) or nucleotide sequence analysis (13, 20, 29) have shown them to be practically identical. Likewise, the polypeptides of KHV isolates from different geographic areas were similar, although one isolate from Israel had two additional polypeptides (7, 9).

The virus is inactivated by UV radiation and temperatures above 50°C for 1 minute. The following disinfectants are also effective for inactivation: iodophore at 200 mg/litre for 20 minutes, benzalkonium chloride at 60 mg/litre for 20 minutes, ethyl alcohol at 30% for 20 minutes and sodium hypochlorite at 200 mg/litre for 30 seconds, all at 15°C (21).

b) Host factors

Naturally occurring KHV infections have only been recorded from common carp (*Cyprinus carpio carpio*), koi carp (*Cyprinus carpio koi*) and ghost carp (*Cyprinus carpio goi*) and hybrids of these varieties. All age groups of fish appear to be susceptible to KHVD (4, 29, 36), but under experimental conditions, 2.5–6 g fish were more susceptible than 230 g fish (26). Differential resistance to KHVD has been shown among different common carp strains (32) and other studies have suggested an age-related resistance (26). Morbidity of affected populations can be 100%, and mortality 70-80% (4, 38), but the latter can be as high as 90 or 100% (4, 37).

Carp are often raised in polyculture with other fish species, but no signs of disease or mortalities have been observed in those other fish, during KHVD outbreaks, under normal polyculture conditions. Refractory species include goldfish (*Carrassius auratus*), grass carp (*Ctenopharyngodon idellus*), silver carp (*Hypophthalmichthys molitrix*), tench (*Tinca tinca*), sturgeon (*Acipenser* sp.) Nile tilapia (*Oreochromis niloticus*), silver perch (*Bidyanus bidyanus*) and channel catfish (*Ictalurus punctatus*) (4, 17, 26, 35).

The disease is temperature dependent, occurring between 16–25°C (6, 17, 26, 29, 36, 37). Under experimental conditions the disease has caused high mortality at 28°C (10) but not at 29 or 30°C (19, 25), nor at 13°C (10). However, viral DNA was detected in the fish by PCR at 13°C, and it is possible that infected fish surviving at low temperatures may be reservoirs of the virus (10). The disease course can be rapid. The disease manifested itself in 3 days following the addition of naïve fish to a pond containing diseased fish (38), but usually under those circumstances it takes 8–21 days for the disease to be observed in the naïve fish (4, 17). It is not known whether under natural conditions survivors of KHVD are persistently infected with virus, and if so, whether they shed the virus or for how long the fish retain the virus. Some of these aspects have been investigated in experimentally infected fish where it was shown that virus could persist in common carp infected at a permissive temperature and subsequently maintained at a lower than permissive temperature (33).

Common carp (*Cyprinus carpio*) strains are currently the only reported host of KHVD and therefore considered to be most susceptible to KHV infection. Goldfish x common carp hybrids, produced by hybridising male goldfish with female carp, have been reported to show some susceptibility to KHV infection. Approximately 50% of these hybrids examined at 25 days after intraperitoneal injection with a high dose of KHV possessed viral genomic DNA, as detected by PCR (18). In contrast to findings elsewhere, recent experimental data from Germany suggests a susceptibility of goldfish and grass carp to KHV but further confirmation of these findings are needed (14, 18). When sampling during surveillance programmes for KHV, common carp or strains such as koi or ghost (koi × common) carp should be preferentially selected followed by any common carp hybrids present on the site such as goldfish × common carp. Cyprinid species are commonly mixed together in polyculture systems and the risk of transmission of virus

between species, during disease outbreaks, is high. If the findings from Germany were confirmed then, for disease surveillance purposes, all cyprinid species would need to be considered as potential covert carriers of KHV.

The reservoirs of KHVD are clinically infected fish and covert virus carriers among cultured, feral or wild fish. Virulent virus is shed via faeces, urine, gill and skin mucus. However, gill, kidney, and spleen are the organs in which KHV is most abundant during the course of overt infection (10).

The mode of transmission of KHV is horizontal but 'egg-associated' transmission (usually called 'vertical' transmission) cannot currently be ruled out. Horizontal transmission may be direct (fish to fish) or vectorial, water being the major abiotic vector. However, animate vectors (e.g. parasitic invertebrates and piscivorous birds and mammals) and fomites may also be involved in transmission.

c) Disease pattern

Disease patterns are influenced by water temperature, virulence of the virus, age and condition of the fish, population density and stress factors. The immune status of the fish will also be an important factor with both non-specific (interferon) and specific immunity (serum antibodies, cellular immunity) having important roles in herpesvirus infections. Clinical disease dominates at water temperatures above 18°C when the host immune response is at its optimum. Infected carp produce antibodies against the virus, which have been detected by ELISA methods at high serum dilution. Antibody has been detected in the serum at 3 weeks after experimental infection and in survivors after 1 year following a natural infection (1, 28, 33). Secondary and concomitant bacterial and/or parasitic infections are commonly seen in diseased carp and may affect the mortality rate and display of signs (15).

Following the first reports of KHVD in Israel and Germany (4, 16, 26) the geographical range of the disease has become extensive. The disease has been spread to many countries world-wide, predominantly through the trade in Koi carp before the current knowledge of the disease and means to detect it were available. It is now known to occur in, or has been recorded in fish imported into at least 21 different countries. In Europe this includes Austria, Belgium, Denmark, France, Italy, Luxembourg, The Netherlands, Poland, Switzerland and the United Kingdom (3, 6, 15, 30). In Asia, China (Hong Kong) (15), Indonesia (35), Japan (29), Malaysia (15, 22, 23), Singapore (in fish imported from Malaysia), Taipei China (37) and Thailand (in fish imported into Germany, 15). Elsewhere, South Africa (15) and the United States of America (11, 16, 36) have reported occurrence of KHVD. It is likely that the virus is present in many more countries, but has not yet been identified there or reported.

d) Control and prevention

Methods to control KHVD should mainly rely on avoiding exposure to the virus coupled with good hygiene and biosecurity practices. This is feasible on small farms supplied by spring or borehole water and a secure system to prevent fish entering the farm via the discharge water. Biosecurity measures should also include ensuring that new introductions of fish are from disease free sources and a quarantine system where new fish are held with sentinel fish at permissive temperatures for KHVD. The fish are then quarantined for a minimum of 4 weeks to 2 months before transfer to the main site and mixing with naïve fish. Hygiene measures on site should be similar to those recommended for SVC and include disinfection of eggs by iodophore treatment (21), regular disinfection of ponds, chemical disinfection of farm equipment, careful handling of fish to avoid stress and safe disposal of dead fish.

In rearing facilities with a controlled environment, elevation of water temperature above 26–28°C can reduce mortalities during KHVD outbreaks (7, 28). Lowering the stocking density, and treating secondary infections may also help reduce the severity of the disease (35) A safe and effective vaccine is not currently widely available. However, attenuated virus has been used to vaccinate carp and protect the fish from virus challenge (25, 28). The vaccine preparation induced antibody against the virus, but the duration of the protection is unknown. The vaccine is currently licensed for use in Israel and has been widely used in carp farms across the country.

3. Diagnostic methods

Diagnosis of KHVD in clinically affected fish can be achieved by virus isolation. However, the virus is isolated in only a limited number of cell lines and these cells can be difficult to handle. Also, cell

culture isolation is not as sensitive as the published PCR-based methods to detect KHV DNA and is not considered to be a reliable diagnostic method for KHVD (15). Immunodiagnostic methods, similar to those used for diagnosis of SVC (e.g. immunofluorescence [IF] tests or ELISAs), may be suitable for rapid identification and diagnosis of KHVD but have not been extensively reported, compared or validated. Until such time as validated tests are available, diagnosis of KHVD should not rely on just one test but a combination of two or three tests (15).

KHV infection produces a detectable antibody response in carp and enzyme immunoassays that reliably detect these antibodies have been published (1, 28). These methods can be used as rapid presumptive tests during the acute disease, however various parameters, such as antibody sensitivity and specificity and sample preparation, can influence the results and therefore a negative result should be viewed with caution.

Detection of antibodies may prove to be a valuable method of establishing previous exposure to KHV in apparently healthy fish, and until PCR-based methods have been developed that are able to reliably detect persistent virus in exposed fish, antibody assays may be the only surveillance tools available. However, due to insufficient knowledge of the serological responses of fish to virus infections, the detection of fish antibodies to viruses has not thus far been accepted as a routine screening method for assessing the viral status of fish populations. Validation of some serological techniques for certain fish virus infections could arise in the near future, rendering the use of fish serology more widely acceptable for health screening purposes.

Fish material suitable for virological examination is:

- **Asymptomatic fish** (apparently healthy fish): Gill, kidney, spleen, and encephalon (any size fish).
- **Clinically affected fish:** Gill, kidney, spleen, gut and encephalon (any size fish).

a) Field diagnostic methods

During a KHVD outbreak there will be a noticeable increase in mortality in the population. All age groups of fish appear to be susceptible to KHVD, although, generally, younger fish up to 1 year are more susceptible to clinical disease. Fish become lethargic, separate from the shoal and gather at the water inlet or sides of a pond and gasp at the surface of the water. Some fish may experience loss of equilibrium and disorientation but they may also show signs of hyperactivity. On closer examination of individual fish, typical clinical signs include pale discolouration or reddening of the skin, which may also have a rough texture, focal or total loss of epidermis, over- or under-production of mucus on the skin and gills. Other gross signs include enophthalmia (sunken eyes) and haemorrhages on the skin and base of the fins and fin erosion.

b) Clinical methods

There are no pathognomic gross lesions. Final diagnosis must await direct detection of viral DNA or antigen in tissues or virus isolation and identification. However, the most consistent gross pathology is seen in the gills and this can vary in extent from pale necrotic patches to extensive discolouration, severe necrosis and inflammation. Further examination can reveal erosion of primary lamellae, fusion of secondary lamellae, and swelling at the tips of the primary and secondary lamella. Other internal lesions are variable in occurrence and often absent in cases of sudden mortality. Other gross pathologies that have been reported include adhesions in the abdominal cavity with or without abnormal colouration of internal organs (lighter or darker). The kidney or liver may be enlarged, and they may also exhibit petechial or focal haemorrhages.

Presence of gross pathologies may also be complicated because diseased fish, particularly common carp, are also infested with ectoparasites such as *Argulus* sp., *Chilodonella* sp., *Cryptobia* sp., *Dactylogyrus* sp., *Gyrodactylus* sp., *Ichthyobodo* sp., *Ichtyophthirius* sp., *Trichodina* sp. and gill monogeneans, as well as numerous species of bacteria.

The histopathology of the disease can be non-specific and variable, but inflammation and necrosis of gill tissues is a consistent feature. Gills also exhibit hyperplasia and hypertrophy of branchial epithelium, and fusion of secondary lamellae and adhesion of gill filaments can be seen. Necrosis, ranging from small areas of necrotic epithelial cells of secondary lamellae to complete loss of the lamellae is observed. Branchial epithelial cells and leucocytes may have prominent nuclear swelling, margination of chromatin to give a "signet ring" appearance and pale diffuse eosinophilic intranuclear inclusions have been observed. Inflammation, necrosis and nuclear inclusions have been observed (individually or together) in other organs, particularly the kidney, but also in the spleen, pancreas, liver, brain, gut and oral epithelium.

c) Agent detection and identification methods

Detailed methods are not presented here because there have not been extensive comparison and validation of detection and identification methods for KHV. However, a short description of available published methods is provided. Method recommendations will rely on further testing and validation and further data being obtained from laboratories that have developed the methods to decide if they are 'fit-for-purpose'.

- **Direct detection methods**

i) Isolation of KHV in cell culture

The virus can be isolated in a limited number of cell cultures, but cell culture isolation is not as sensitive as PCR and is not considered to be a reliable diagnostic method for KHVD (15).

The virus replicates in koi fin cells (KF-1) (17), carp fin (CaF-2) and carp brain (CCB) cells (24), and in primary cells from fins of common or koi carp (19, 26, 28). Other cell lines used routinely for isolation of fish pathogenic viruses such as EPC, FHM, BF-2, CHSE-214 and RTG-2 cells are refractory to the virus (4, 19, 24, 37). The virus is most abundant in gill, kidney, and spleen tissues during the course of overt infection (10) and it is recommended to sample these tissues for virus isolation. The optimum incubation temperature for virus isolation in KF-1 or CCB cells is 20°C but 8–12 days' incubation may be required before a cytopathic effect (CPE) is observed (7).

ii) Identification of virus isolated in cell culture

Viruses isolated in cell culture must be definitively identified, as a number of different viruses have been isolated from carp exhibiting clinical signs resembling those of KHVD (5, 15).

Rapid presumptive methods

Immunodiagnostic methods, similar to those used for presumptive identification of SVC (e.g. IF tests or ELISAs), may well be suitable for rapid identification and diagnosis of KHVD (27, 32).

Confirmatory identification methods

The most reliable method for confirmatory identification is by PCR, or one of its variants, which have also been used to identify KHV DNA directly in fish tissues (2, 8–11, 13, 19, 20, 27, 40).

A PCR based on the thymidine kinase (TK) gene of KHV was reported to be more sensitive than PCR methods described by Gilad *et al.* (9) and Gray *et al.* (11), and could detect 10 fg of KHV DNA (2); the PCR of Ishioka *et al.* (20), based on the DNA polymerase gene, detected 100 fg of KHV DNA. The loop-mediated isothermal amplification (LAMP) method (13) was also based on the KHV TK gene, and was as sensitive as a PCR method developed by the same authors, but was more rapid than the PCR. The PCR described by Gray *et al.* (11) was improved by Yuasa *et al.* (40), and has been incorporated in the official Japanese guidelines for the detection of KHV.

New improved diagnostic PCR tests will continue to be developed and it is hoped that they will be validated as recommended in Chapter 1.1.3 of this *Aquatic Manual.*

The DNA extraction and PCR protocols detailed below for direct detection of KHV in fish tissues are also suitable for confirmatory identification of infected cell culture supernatants.

iii) Diagnostic methods for clinically diseased fish

Direct detection in fish tissues

KHV has been identified in touch imprints of liver, kidney and brain of infected fish by IF. Highest levels of positive immunofluorescence was seen in the kidney and the virus could be detected by IF on a kidney imprint 1 day post-infection (27, 32). Virus antigen has also been detected in infected tissues by an immunoperoxidase staining method. The virus antigen was detected by 2 days post infection in the kidney, and was also observed in the gills and liver (27). However, the detection of KHV by immunostaining must be interpreted with care, as positive staining cells could result from cross-reaction with serologically related virus (e.g. CyHV-1) or a non-viral protein (27).

ELISA-based methods for direct detection of KHV antigen in infected tissues are under development in a number of laboratories worldwide but no methods have been published.

The most commonly used method for detection of KHV directly in fish tissues is using PCR assays specific for KHV (see above, under confirmatory identification).

In studies carried out at the Cefas Weymouth laboratory, published primer sets were compared using a standard PCR protocol for detection of KHV DNA in carp tissues (K. Way, unpublished data). The primer set targeting the TK gene (2) was the most sensitive with a detection limit three log greater than Gilad primers. CNGV primers (27) and modified Gray SpH primers that target short regions of the genome (109 bp and 151 bp, respectively) also performed well, particularly on decomposed tissues. The TK primer set later performed well in a method ring-trial carried out in 21 laboratories in 19 countries around the world (K. Way, unpublished data).

The same study at Cefas and the method ring-trial also compared commercial DNA extraction kits for their ability to provide KHV DNA of sufficient quality for the PCR. Of the commercial kits tested at Cefas, EasyDNA (Invitrogen), DNeasy (Qiagen) and DNAzol reagent (Invitrogen) all extracted DNA of suitable quality. In the ring-trial, the High Pure PCR template preparation kit (Roche), QIAamp DNA blood minikit (Qiagen) and the Puregene DNA purification kit, all performed well. However, some laboratories found the DNAzol reagent not to be as reliable.

The sample preparation protocol detailed below uses the DNAzol reagent for extraction of KHV DNA. This is an easy to use, short duration protocol that is also relatively inexpensive compared to some kits. Laboratories that are not familiar with DNAzol extraction may find the method less reliable in their hands. However, a number of DNA extraction kits are available commercially (including those listed above) that will produce high quality DNA suitable for use with the PCR protocol detailed.

The PCR protocol detailed below uses the TK primer set developed by Bercovier and colleagues at the Hebrew University-Hadassah Medical School in Israel (2). Of the published single-round-PCR methods, this is currently considered to be the most sensitive for detection of KHV DNA in fresh tissue samples from clinically diseased carp. This protocol may also allow detection of subclinical levels of virus. If the tissue shows evidence of decomposition then primer sets (see above) targeting shorter regions of the genome may need to be used in place of the TK primer set.

General notes

PCR is prone to false-positive and false-negative results. Therefore each assay and tissue extraction should include a negative control to rule out contamination. To further minimise the risk of contamination, aerosol-preventing pipette tips should be used for all sample and PCR reaction preparation steps.

Sample preparation

i) Virus extraction from organ tissues should be carried out using the procedure described in Chapter I.1 (Section B.3.2).

ii) Add 100 µl of tissue homogenate (1/10 [w/v]) or virus culture supernatant to a 1.5 ml microcentrifuge tube containing 1 ml DNAZOL® reagent.

iii) Mix gently by inverting the tube five times and stand at room temperature for 5 minutes then centrifuge at 10,000 rpm for 10 minutes using a microcentrifuge.

iv) Remove 1 ml of the supernatant to a new 1.5 ml microcentrifuge tube containing 0.5 ml of ethanol.

v) Mix gently by inverting the tube five times and stand at room temperature for 5 minutes, then centrifuge at 13,000 rpm for 30 minutes using a microcentrifuge.

vi) Remove the supernatant and rinse the pellet with 250 µl of 70% ethanol in molecular biology grade water.

vii) Spin samples for 5 minutes at 13,000 rpm.

viii) Remove the ethanol using a pipette and air-dry the pellet by leaving the tubes open on the bench for 5 minutes.

ix) Resuspend the pellet in 50 µl molecular biology grade water, prewarmed at 60°C, and incubate at 60°C for 5 minutes. Samples can be stored at –20°C until required.

PCR

All PCR reactions are prepared in a clean area that is separate from the area where the amplifications are performed. This will minimise the risk of contamination.

i) For each sample prepare a master mix containing:

For Go Taq Polymerase:

10 µl	Reaction buffer (×10 conc.)
5 µl	$MgCl_2$ (25 mM stock)
0.5 µl	dNTPs (25 mM mix) [Promega Cat.no.U1240]
0.5 µl	Forward primer (100 pmol/µl stock)
0.5 µl	Reverse primer (100 pmol/µl stock)
0.25 µl	Go Taq polymerase 500 µ (5 µ/µl) [Promega Cat.no.M8305]
30.75 µl	Molecular biology grade water

Bercovier TK primers:

Forward = 5'-GGG-TTA-CCT-GTA-CGA-G-3'

Reverse = 5'-CAC-CCA-GTA-GAT-TAT-GC-3'

Product size = 409 bp

For each sample dispense 47.5 µl into a 0.5 ml thin walled microcentrifuge tube. Overlay with two drops of mineral oil.

ii) Add 2.5 µl of the DNA extracted DNAzol®. Store the remainder of the DNA at –20ºC.

iii) Place tubes in a thermal cycler and perform programme:

1 cycle of: 5 minutes at 94ºC

40 cycles of: 1 minute at 95ºC

1 minute at 55ºC

1 minute at 72ºC

Followed by a final extension step of 10 minutes at 72ºC.

iv) Electrophorese 20 µl volumes of PCR product on a 2% ethidium bromide stained agarose gel (4% when separating smaller amplification products of <300 bp) at 120 V for 20 minutes and visualise under UV light. An appropriate molecular weight ladder should be included on the gel to determine the size of the product.

v) Products of the correct size should be confirmed as KHV in origin by sequence analysis.

4. Rating of tests against purpose of use

The methods currently available for surveillance, detection and diagnosis of KHVD are listed in Table 1. The designations used in the table indicate: A = the method is currently the recommended method for reasons of availability, utility and diagnostic sensitivity and specificity; B = the method is a standard method with good diagnostic sensitivity and specificity; C = the method has application in some situations, but cost, accuracy or other factors severely limits its application; D = the method is currently not recommended for this purpose. Although not all of the tests listed as category A or B have undergone formal standardisation and validation (at least stages 1 and 2 of figure 1 of Chapter 1.1.2), their routine nature and the fact that they have been used widely without dubious results makes them acceptable.

Table 1. *KHVD surveillance, detection and diagnostic methods*

Method	Surveillance to declare freedom from infection	Presumptive diagnosis of infection or disease	Confirmatory diagnosis of infection or disease
Gross signs	D	B	D
Histopathology of tissues and organs	D	B	C
Isolation of in cell culture	D	C	D
Antibody-based assays to detect KHV antigen (IFAT, ELISA)	D	B	C
Transmission EM of tissues	D	B	C
PCR of tissue extracts*	C	A	A
PCR – sequence analysis	NA	C	A
Detection of KHV antibodies in exposed fish (ELISA)**	C	C	D

IFAT = Indirect fluorescent antibody test; ELISA = enzyme-linked immunosorbent assay;
EM = electron microscopy; PCR = polymerase chain reaction.

*Diagnostic virologists should be aware that fish recently vaccinated against KHV may test positive by PCR. No information is currently available to indicate any genome sequence differences between the attenuated vaccine strain and wild-type (w.t.) KHV. Until this sequence information is provided, diagnostic laboratories will not be able to distinguish between w.t. and vaccine strain of KHV and this could lead to a false diagnosis.

**Diagnostic virologists should be aware that fish recently vaccinated against KHV may test positive by ELISA. There may also be a low-level cross reaction with antibodies to CyHV-1.

NOTE: Many diagnostic laboratories may encounter difficulties in obtaining antibodies against KHV that are suitable for use in immunodiagnostic tests. However, a limited number of monoclonal and polyclonal antibodies may be very soon available from commercial sources. It is quite likely that diagnostic kits will also soon be available from the same sources.

5. Corroborative diagnostic criteria

a) Definition of suspect case

A suspect case of KHVD is defined as the presence of typical clinical signs of the disease in a population of susceptible fish OR presentation of typical histopathology in tissue sections OR typical CPE in cell cultures without identification of the causative agent OR a single positive result from one of the diagnostic assays described above.

b) Definition of confirmed case

A confirmed case is defined as a suspect case with subsequent identification of the causative agent by one of the serological or molecular assays described above OR a second positive result from a separate and different diagnostic assay described above.

6. Diagnostic/detection methods to declare freedom

There are no currently recommended methods for surveillance of susceptible fish populations for declaration of freedom from KHV. However, many laboratories are investigating further development of molecular-based methods to increase sensitivity (e.g. real-time and nested PCR) or to reliably detect low levels of persistent virus DNA. These assays may well prove suitable for surveillance programmes.

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NB: There are OIE Reference Laboratories for Koi herpesvirus disease (see Table at the end of this *Aquatic Manual* or consult the OIE Web site for the most up-to-date list: www.oie.int).